

Guide to the Implementation of Quality Management Systems for National Meteorological and Hydrological Services and Other Relevant Service Providers

2017 edition

WEATHER CLIMATE WATER



WORLD
METEOROLOGICAL
ORGANIZATION

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EDITORIAL NOTE

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Chairperson, Publications Board
World Meteorological Organization (WMO)
7 bis, avenue de la Paix
P.O. Box 2300
CH-1211 Geneva 2, Switzerland

Tel.: +41 (0) 22 730 84 03
Fax: +41 (0) 22 730 81 17
Email: publications@wmo.int

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PREFACE

This 2017 edition of the WMO *Guide to the Implementation of Quality Management Systems for National Meteorological and Hydrological Services and Other Relevant Service Providers* (WMO-No. 1100) is one of the main deliverables agreed at the sixty-eighth session of the Executive Council (15–24 June 2016, Geneva) for furthering the WMO quality management framework (WMO, 2016, Decision 76).

The objective of this publication is to provide guidance to WMO Members on how to develop and implement a quality management system (QMS). It also provides the steps for transition from International Organization for Standardization (ISO) standard ISO 9001:2008 (ISO, 2008) to standard ISO 9001:2015 (ISO, 2015c). It is especially focused on WMO Member National Meteorological and Hydrological Services (NMHSs). However, it could be successfully utilized by other service providers, such as non-NMHS aeronautical meteorological service providers, and is also applicable to the management of relevant WMO programmes by WMO constituent bodies.

There is sufficient evidence that a QMS can help to enhance the quality of NMHS activities including streamlining and optimizing the processes and procedures applied and the products and services provided. This Guide details the steps required to obtain certification of compliance with the ISO standard ISO 9001:2015, *Quality Management System – Requirements* (ISO, 2015c).

It is essential that this Guide is used in conjunction with the ISO 9001:2015 standard, which was published in September 2015 and which will fully replace the ISO 9001:2008 standard in September 2018. In this regard, the publication of this Guide is timely to assist Members to successfully transition existing QMSs based on the 2008 ISO standard to the 2015 standard.

The Guide is based on significant practical experience gained during the development and implementation of QMSs. The associated resource materials given in the appendices are the result of development of tools that have proven useful in meeting the requirements of ISO 9001:2015.

This Guide is published as an online resource document by the WMO E-Library (<https://library.wmo.int/opac/index.php>). Wherever possible, the Guide provides hyperlinks to other resources to ensure its longevity in terms of currency and ongoing value.

Sincere thanks are expressed to the lead authors, Mr Bryan Boase and Ms Helen Tseros, from the Bureau of Meteorology (Australia), for their dedication and leadership in many WMO quality management framework activities and for the high quality of this new edition of the Guide. The work of peer reviewers Mr Gerold Fletzer (Austrocontrol, Austria), Mr Boon-Leung Choy, Mr Lap-Shun Lee and Mr Chi-Tai Shum (Hong Kong Observatory, Hong Kong, China) is also appreciated. The WMO Secretariat staff involved in the publication of this Guide were Mr Dimitar Ivanov and Mr Greg Brock.

1. INTRODUCTION

1.1 Brief history of quality management

1.1.1 The quality movement has its roots back in medieval Europe, in the late thirteenth century, where craftsmen organized themselves into guilds. Until the early nineteenth century, manufacturing in the industrialized world continued to follow this guild model. In the mid-1750s, the factory system, which emphasized product inspection, was introduced in Great Britain and developed into the Industrial Revolution in the early 1800s. The Industrial Revolution led to a system in which large groups of people that performed similar work were brought together under the supervision of an individual, who was appointed to control the quality of work being undertaken.

1.1.2 During the mid-1920s, Walter Shewhart, a statistician with Bell Laboratories, broadened the focus on quality to include not only the finished product but also the processes needed to achieve that quality. He recognized that the processes provided useful data that could be analysed using statistical techniques to ascertain whether a process was providing the optimum outcome or required refinement to deliver the expected level of quality. To this day, that activity still plays a key role in any quality management system (QMS).

1.1.3 Another statistician, William Edwards Deming, sometimes referred to as the “father of quality management”, was an advocate of Shewhart’s methods and became a leader of the quality movement in both Japan and the United States of America. Deming triggered a revolution in manufacturing, which led to a significant improvement in product quality. His influence in Japan, through his quality management (QM) initiatives, was a key driving force behind the country’s economic rise in the period after World War II. In the 1970s, many major public and private sector organizations published their own QM standards, which introduced the idea that confidence in a product could be gained through the use of an approved QMS and quality manuals.

1.1.4 Growing international trade stimulated the development of internationally recognized QM standards. It was feared that a variety of national standards would emerge and become a barrier to international trade. It was therefore recognized that there was a need for an international standardization system, which led to the establishment of the International Organization for Standardization (ISO). Today, this is an independent, non-governmental organization, and its members are standards organizations within more than 160 member countries. It is responsible for the development and maintenance of the ISO 9000 series of quality assurance standards, which are the cornerstone of subject matter being considered here.

1.2 Drivers for adopting a quality management approach – WMO and International Civil Aviation Organization perspectives

1.2.1 The adoption of a QM approach to the delivery of National Meteorological and Hydrological Services (NMHSs) products and services was driven by a number of imperatives. A key one was the International Civil Aviation Organization (ICAO) requirements relative to the delivery of aeronautical meteorological services. A detailed overview of the ICAO drivers for adopting a QM approach is given in the annex below.

1.2.2 Quality management was first addressed by WMO in May 2003, at the fourteenth World Meteorological Congress (WMO, 2003). The Congress adopted Resolution 27 (Cg-XIV) – *Quality Management*, and decided that WMO should work towards a quality management framework for NMHSs that would include the following elements to be dealt with on a phased basis:

- (a) WMO technical regulations;
- (b) QMSs, including quality control;
- (c) Certification procedures.

The Congress also requested the Executive Council to guide the development of the WMO quality management framework (WMO-QMF) by providing broad guidelines for NMHSs on how to develop their QMSs.

1.2.3 In October 2004, a WMO workshop on QM was held in Malaysia to address the recommendations of the fifty-sixth session of the Executive Council, in particular the adoption of the WMO-QMF (WMO, 2005). An Inter-Commission Task Team on the Quality Management Framework was established to oversee and coordinate the activities and monitor progress of the WMO-QMF as it was developed and implemented. In November 2005, a WMO seminar on QM, focusing on the provision of meteorological services to aviation, was held in Hong Kong, China.

1.2.4 The first session of the task team was held in April 2005. The meeting reviewed possible ways of establishing closer working relations with ISO in order to develop technical standards relevant to WMO, which would broaden the application and recognition of WMO standards. The meeting recommended that WMO be recognized as an international standardization body by ISO.

1.2.5 The aim of the recognition by ISO was to strengthen the development of international standards and to avoid duplication of work on standards related to meteorological, climatological, hydrological, marine and related environmental data, products and services. WMO is now recognized by ISO as an international standardization body (see ISO Council Resolution 43/2007, approved in December 2007). The working arrangements between ISO and WMO are given in *Agreements and Working Arrangements with other International Organizations* (WMO, 2002). WMO and ISO may now develop, approve and publish common standards based on WMO technical regulations, manuals and guides, which will clarify the authority of WMO documents and enhance their international recognition and dissemination.

1.2.6 At the early stages of the WMO-QMF, there was a misconception that the adoption of a QM approach to the delivery of products and services could be an expensive activity, which may increase significantly the workload and add extra layers of bureaucracy. However, if it is well planned, appropriately resourced and efficiently implemented, the QM approach has been proven by WMO Members to provide a cost-effective management system that brings tangible benefits to NMHSs. Importantly, WMO has noted that the adoption of a QMS should be a strategic decision to meet the specific needs and objectives of Member NMHSs, whose activities and size will influence the development and implementation of the QMS.

1.2.7 It is of considerable note that there was an accelerated implementation of QMSs for the delivery of aeronautical meteorological services during the period 2011–2017, with more than 80% of Member aeronautical meteorological service providers indicating that they had developed QMSs in conformity with the ISO 9001 standard.

1.2.8 These QMSs provide a solid foundation on which to build and expand the suite of products and services delivered by WMO Members. It has now been realized that QMSs should be implemented for service areas beyond aviation, which was promoted through the WMO Strategy for Service Delivery approved by the sixteenth World Meteorological Congress in 2011 (WMO, 2011).

1.2.9 WMO develops and promulgates a comprehensive set of WMO technical regulations and related guidance documents, which provides a good basis for globally harmonized governance and delivery of products and services. In addition, the ISO 9001 standard provides a rigorous management framework that will enable WMO Member NMHSs and other relevant providers to identify and meet the requirements of customers, monitor and measure performance, and identify opportunities to continually improve service delivery.

1.3 **WMO quality management framework**

1.3.1 A document providing a comprehensive background to the WMO-QMF is provided on the WMO QM website (http://www.bom.gov.au/wmo/quality_management.shtml; Australian Government, Bureau of Meteorology, 2017).

1.3.2 This Guide provides practical and detailed information on the application and intent of the WMO-QMF for WMO and its Members.

2. INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

2.1 Introduction

2.1.1 International standardization started in 1906 with the International Electrotechnical Commission, which focused on the electrotechnical field. The International Federation of the National Standardizing Associations, which had a strong focus on mechanical engineering, was formed in 1926 but was disbanded in 1942 during World War II.

2.1.2 In 1946, delegates from 25 countries met in London and decided to create a new international organization, whose objective would be to facilitate the international coordination and unification of industrial standards. The new organization – ISO – officially began operation on 23 February 1947.

2.1.3 This organization is the world's largest developer of international standards, and since 1947, it has published more than 18 500 standards, in areas ranging from agriculture, construction, mechanical engineering and medical devices, to the newest forms of information technology.

2.1.4 There are currently more than 160 ISO members divided into the categories of member bodies, correspondent members and subscriber members.

2.1.5 As the acronym for the International Organization for Standardization would have varied, depending on the language used (for example, IOS in English and OIN in French (Organization internationale de normalization)), the founders of the organization chose a short, all-purpose name – ISO – derived from the Greek *isos*, which means equal. As a result, whatever the country or language, the short form of the organization's name is always ISO.

2.1.6 For further information regarding ISO, see the book *Friendship Among Equals* (Latimer, 1997). The ISO website (<http://www.iso.org/iso/about.htm>) also offers a wealth of useful information.

2.2 The ISO 9000 family of standards

2.2.1 In 1987, an ISO committee chaired by Canada developed an international quality standard based on the then British Standard BS 5750, which was the first of the ISO 9000 series. Since 1987, this series has grown and now includes associated guidelines applicable to particular industries.

2.2.2 The ISO 9000 family comprises two kinds of QM standards: requirements and guidelines. The series consists of the following three standards, which represent international consensus on good QM practices:

- (a) **ISO 9000:2015**, *Quality Management Systems – Fundamentals and Vocabulary* (ISO, 2015b). This standard describes the fundamentals of QMSs and specifies the terminology used in ISO 9000.
- (b) **ISO 9001:2015**, *Quality Management Systems – Requirements* (ISO, 2015c). These requirements can be applied to all types of organizations, both in the public and private sectors, regardless of size or industry group. Therefore, they are generic in nature and can be adopted by, and adapted to, almost any organization; this most certainly includes WMO Member NMHSs and their activities. They can achieve standards of quality that are

internationally recognized and respected throughout the world. It is the only standard in the ISO family against which organizations can be certified (or registered), through a third-party audit process.

- (c) **ISO 9004:2009**, *Managing for the Sustained Success of an Organization – A Quality Management Approach* (ISO, 2009a). This standard focuses on achieving sustainable success in today's complex, demanding and ever-changing environment by meeting the needs and expectations of customers and other stakeholders. An interesting facet of this standard is that it promotes self-assessment as an important tool, which enables ongoing review of the level of maturity attained by QMSs. However, it should be noted that the self-assessment tool is not a substitute for a third-party audit process, which is fundamental to ISO 9001.

Note that the year denoted in the above, and in other ISO standards, represents the year in which the standard was introduced by ISO. For example, ISO 9001:2015 represents the ISO 9001 series of quality assurance standards introduced by ISO in 2015. It should be further noted that, in many cases, the year denoted does not necessarily represent the first year or even subsequent years of introduction of the standard. For example, in the case of ISO 9001, there have been two prior editions (in 2000 and 2008) leading up to the 2015 edition. Details on how and where to obtain copies of the ISO standards and publications are provided in section 2.7 below.

2.3 Importance of the ISO 9000 family of standards

2.3.1 The ISO 9000 family of standards, in particular ISO 9001, is important because of its international orientation. It has the support of national standards bodies from more than 160 countries and is therefore the logical choice for an organization such as WMO. The ISO 9000 family of standards is also recommended to WMO Members as a good practice for their NMHSs and other relevant service-oriented agencies. WMO programmes and WMO Member NMHSs operate in an international environment and have customers who demand an international standard of excellence.

2.3.2 The adoption of a QM approach to the delivery of products and services may require the implementation of a change management strategy. The ISO 9001 standard provides an appropriate framework to implement the required change management processes. The framework helps to identify the most-appropriate policies, procedures, records, technologies, resources and structures needed to achieve and enhance the quality of processes, procedures, products and services. The development and successful implementation of a QMS will instil a quality attitude at all levels of an organization, which, in turn, will help to ensure the delivery of products and services of an international standard.

2.4 Corporate governance and ISO 9001

2.4.1 In simple terms, governance relates to the processes and structures that ensure an organization is directed, controlled and held to account. It focuses on how an organization is managed, how risk is monitored and mitigated, and how value is added for the community, government and other stakeholders.

2.4.2 WMO and its Members predominantly operate in a robust but often rigid public-sector environment. The governance in these sectors covers a wide spectrum of activities focusing on how an organization meets the requirements of legislation and its government-determined outcomes, how it expresses its culture and values, and how it discharges its stewardship responsibility by being open, accountable and prudent in decision-making, in providing policy advice as required, and in managing the delivery of programmes.

2.4.3 Good public-sector governance provides a foundation for high performance, strengthens community confidence in the organization and helps to ensure an organization's reputation is maintained and enhanced. The key components and activities of a sound corporate governance framework are:

- (a) Promoting and ensuring adherence to a code of conduct and values;

- (b) Managing risk;
- (c) Providing continuity of service;
- (d) Ensuring work health and safety;
- (e) Ongoing development of staff competence;
- (f) Providing timely and accurate reports to senior/executive management including government and constituent bodies;
- (g) Contributing to the strategic and operational planning process.

2.4.4 An ISO 9001 QMS provides an excellent management tool to measure and monitor the ongoing performance of an organization's corporate governance activities. Seven key clauses of ISO 9001 enable the requirements articulated within them to be aligned with key corporate governance components. Adopting such a QMS enables the measurement of success or otherwise of corporate governance activities. Figure 1 provides a broad overview of this alignment.

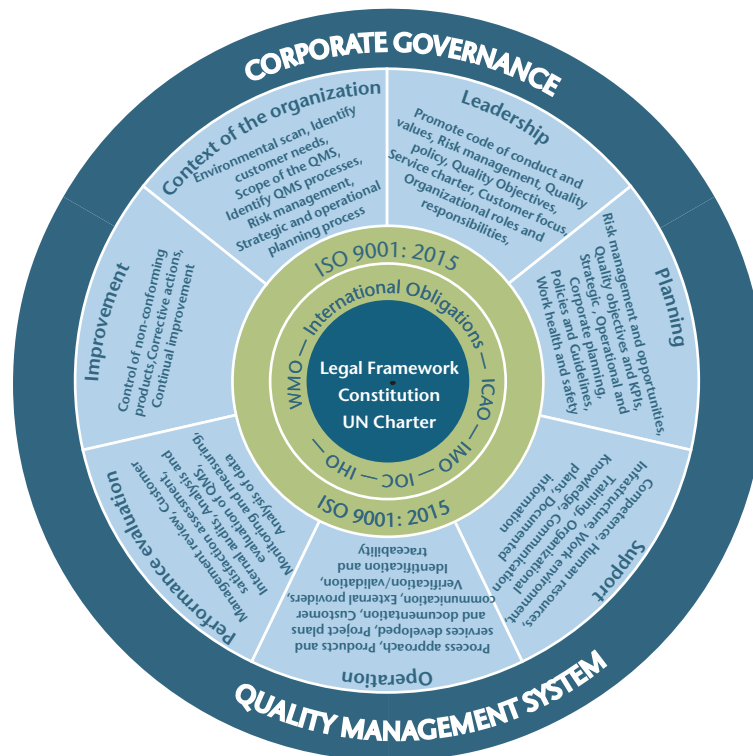


Figure 1. Key clauses of ISO 9001 and their alignment with corporate governance activities (IHO = International Hydrographic Organization, IMO = International Maritime Organization, IOC = Intergovernmental Oceanographic Commission of the United Nations Educational, Scientific and Cultural Organization, UN = United Nations)

2.5 Standard ISO 9001 certification and registration

2.5.1 It is noted by ISO that “certification” refers to the issuing of written assurance (the certificate) by an independent external conformity assessment body that it has audited a management system and verified that it conforms to the requirements specified in the relevant standard (in this case, ISO 9001:2015). “Registration” means that the auditing body records the certification in its client register. Thus, the management system of the organization has been both certified and registered.

2.5.2 The difference between the two terms is not significant, and both are acceptable for general use. However, certification is the term most widely used, while registration is often preferred in North America. The two are often used interchangeably. However, the term “accreditation” should never be used as an alternative for either certification or registration. Accreditation refers to the formal recognition that an organization – termed either an “accreditation body” or “conformity assessment /certification body” – is competent to certify compliance with a specific ISO standard (for example, ISO 9001:2015). Certificates issued by accredited conformity assessment/certification bodies are perceived on the market as having more credibility.

2.5.3 To locate accreditation and/or conformity assessment/certification bodies in an area, a good starting point is the website of the International Accreditation Forum (<http://www.iaf.nu/>), which is the world’s association of conformity assessment accreditation bodies in the fields of management systems, products, services, staff and other similar programmes of conformity assessment. The members and signatories for various countries/regions are given at http://www.iaf.nu/articles/IAF_MEMBERS_SIGNATORIES/4.

2.5.4 When choosing a certification body, the following steps should be undertaken:

- (a) Evaluate several certification bodies. The evaluation should not be based on price alone. It should address quality criteria that include levels of competence and reputation (known performance) within sectors specific to the QMS(s); for example, the aviation and or marine sectors, and experience within the meteorological service environment.
- (b) Check if the certification body uses the relevant [ISO Council Committee on Conformity Assessment standard](#).
- (c) Check if it is accredited as per paragraph 2.5.2 above. If certification is achieved through a non-accredited body, it will not be possible to use an accredited body logo or mark.

2.5.5 According to ISO, the certification process is expected to provide confidence that the organization has a QMS that conforms to the applicable requirements of ISO 9001. In particular, it is expected that the organization:

- (a) Has established a QMS suitable for its products and processes, and which is appropriate for its certification scope;
- (b) Has analysed and understands customer needs and expectations, as well as the relevant statutory and regulatory requirements related to its products;
- (c) Has ensured that product characteristics have been specified in order to meet customer and statutory/regulatory requirements;
- (d) Has determined and manages the processes needed to achieve the expected outcomes (conforming products and enhanced customer satisfaction);
- (e) Has ensured the availability of resources necessary to support the operation and monitoring of these processes;
- (f) Monitors and controls the defined product characteristics;
- (g) Aims to prevent non-conformity and has improvement processes in place to:
 - (i) Correct any occurrences of non-conformity (including product non-conformity detected after delivery);
 - (ii) Analyse the cause of non-conformity and take corrective action to avoid its recurrence;
 - (iii) Address customer complaints;

- (h) Has established an effective internal audit and management review process, and is continually improving the effectiveness of its QMS through monitoring and measuring.

2.6 Benefits of ISO 9001 certification

2.6.1 The benefits of implementing a QMS and achieving certification of compliance with ISO 9001 are significant. It can be demonstrated that the benefits to WMO Member NMHSs and other relevant agencies will far outweigh the initial effort and resources required to develop and implement a QMS. Below are some key benefits enjoyed by organizations with mature QMSs (not listed in order of priority):

- (a) Customer needs identified, met and monitored within a consistent management framework;
- (b) Improved management control and reporting;
- (c) Continuous improvement and enhanced quality culture embedded in the organization;
- (d) Clear processes in place to address poor-quality/non-conforming products;
- (e) Marketing tool for promoting the organization internally and externally, so that it stands out from potential competitors;
- (f) External audit by a third party, which is a powerful tool to establish and imbed the credibility and accountability of an organization;
- (g) Well-defined procedures and processes – employees know what to do and how to do it, and do not waste time duplicating efforts;
- (h) Enhanced teamwork, and internal and external communication;
- (i) Greater clarity of job specifications, descriptions and duties;
- (j) Improved work health and safety practices;
- (k) Greater quality assurance of products and services;
- (l) Enhanced response to customer feedback/complaints to rectify non-conformances;
- (m) The organization functions in a well-organized manner as a result of the systematic approach to the delivery of its products and services and associated activities;
- (n) As the QMS matures, more time is spent on improving products and services, as opposed to rectifying and reacting to the demands of dissatisfied customers;
- (o) Significant decreases in time and money spent on recurring problems, as many are resolved permanently;
- (p) The organization builds the inner resources and skills necessary to identify and resolve problems more expediently;
- (q) Significantly improved documentation processes and procedures that, in turn, enhance the capture of corporate knowledge;
- (r) Improved document control, which enhances the ability of the QMS to produce high-quality responses to the legal community on matters pertaining to requests such as those associated with accident/incident investigations and weather-related insurance claims;
- (s) Competencies are identified, gained and maintained through appropriate training;

- (t) Job satisfaction of employees can be significantly improved;
- (u) The QMS is a powerful change management tool;
- (v) The QMS is a powerful tool to ensure important issues are highlighted at the appropriate organizational level;
- (w) Although no longer a requirement of ISO 9001, those QMSs already maintaining a quality manual have identified it as a useful induction tool for new staff and as a road map for how the QMS operates;
- (x) Risk-based thinking – identifying opportunities and threats;
- (y) Control and monitoring of externally provided processes, products and services;
- (z) Enhanced understanding of the context of the organization – internal and external issues that affect it.

2.6.2 The adoption of a QM approach and certification of compliance with ISO 9001 can deliver a vast range of benefits. However, it should be remembered that the achievement of ISO 9001 certification of compliance is not an end in itself – it is a milestone in the QM journey.

2.7 Standards and publications of the International Organization for Standardization

2.7.1 It is essential that WMO programmes and Member NMHSs adopting a QM approach to their activities and the delivery of products obtain copies of:

- (a) ISO 9000:2015, *Quality Management Systems – Fundamentals and Vocabulary* (ISO, 2015b);
- (b) ISO 9001:2015, *Quality Management Systems – Requirements* (ISO, 2015c);
- (c) ISO 19011:2011, *Guidelines for Auditing Management Systems* (ISO, 2011).

These may be purchased online, as PDF documents, from the ISO store (<http://www.iso.org/iso/store.htm>). As the standards are updated at regular intervals, it should be ensured that the latest edition is obtained.

2.7.2 This Guide should be used in conjunction with the above-mentioned ISO 9001:2015 standard, to ensure the requirements are fully understood and addressed and that maximum benefits are gained.

2.7.3 For information on how ISO develops standards, see the ISO website at <https://www.iso.org/developing-standards.html>.

KEY POINTS



1. The ISO 9000 family of standards, in particular ISO 9001, is useful because of its international orientation. It has the recognition and support of national standards bodies from more than 160 countries.
2. Standard ISO 9001 can be applied to all types of organizations in both the public and private sectors, regardless of size or industry group. It can help both product- and service-oriented organizations achieve standards of quality that are recognized and respected throughout the world.
3. Standard ISO 9001 provides an excellent management tool to measure the ongoing performance and success of the corporate governance activities of an organization.
4. It is essential that copies of ISO 9000:2015, *Quality Management Systems – Fundamentals and Vocabulary* (ISO, 2015b), ISO 9001:2015, *Quality Management Systems – Requirements* (ISO, 2015c), and ISO 19011:2011, *Guidelines for Auditing Management Systems* (ISO, 2011), be obtained.
5. There are significant benefits to be gained throughout the QMS from the adoption of a QM approach and the certification of compliance with ISO 9001.

3. **PRINCIPLES OF QUALITY MANAGEMENT**

3.1 **Overview**

3.1.1 The principles of QM underpin the ISO 9000 standards and need to be embedded in a QMS to provide a sound foundation for achieving the goals and objectives of WMO programmes and Member NMHSs. These principles have been derived from the collective experience and knowledge of international experts who participate in the ISO Technical Committee (ISO/TC 176) responsible for developing and maintaining the ISO 9000 standards.

3.2 **Principles**

3.2.1 A QM principle is a fundamental rule for leading, operating and developing an organization, with the objective of continually improving performance over the long term through a focused approach to all stakeholders, particularly customers. There are seven principles of QM that provide a sound foundation for achieving goals and objectives.

3.2.2 Standard ISO 9001:2015 is based on the seven principles of:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision-making
- Relationship management

3.2.3 As mentioned in paragraph 2.2.2 above, the ISO 9001:2015 standard can be applied to virtually any organization, as can the principles. It is therefore not appropriate within the context of this Guide to attempt to articulate how they should be applied. Each organization will need to apply the principles in terms of their own particular activities. Fortunately, ISO has produced an extremely informative and contemporary document, which provides, for each principle, a description, an explanation of the rationale as to why it is important, and examples of the key benefits and actions that can be taken to improve performance when applying the principles (ISO, 2015c, section 0.2).

3.2.4 It is a useful exercise for organizations adopting a QM approach to review and document their activities in the context of these principles (<https://www.iso.org/files/live/sites/isoorg/files/archive/pdf/en/pub100080.pdf>).

KEY POINT



It is important that the principles of QM form the foundation of an organization's QM approach to activities and delivery of products and services. They should be woven into the processes, outcomes and overall culture of WMO programmes, and those of WMO Member meteorological, hydrological and other relevant agencies.

4. **STANDARD ISO 9001:2015**

4.1 **Overview**

4.1.1 This chapter provides an introduction to ISO 9001:2015, *Quality Management Systems – Requirements* (ISO, 2015c), and then provides insight into the intent of each clause and greater clarity for the reader.

4.1.2 Standard ISO 9001:2015 “applies the framework developed by ISO to improve alignment among its International Standards for management systems”. It is important to note that “there is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations” (ISO, 2015c, Annex A).

4.1.3 The strong advantage of ISO 9001 is that it is designed for third-party certification purposes. When an organization deems that its QMS meets the ISO 9001 requirements, it can appoint an independent certification body (third party) to audit its QMS. If the audit demonstrates that the ISO requirements are met, the QMS will be issued with an official certificate of compliance.

4.1.4 Although WMO does not require certification of compliance, it encourages it as and where appropriate. However, national legislation, stakeholders or partner organizations may require certification of compliance with ISO 9001. For example, ICAO Annex 3 – *Meteorological Service for International Air Navigation* (ICAO, 2016) requires those responsible for the provision of aeronautical meteorological services to be able to demonstrate, via audit, conformity with a quality system. Certification of compliance with the ISO 9001 standard is the most logical and powerful way to demonstrate this.

4.1.5 It should be duly noted that any claim of compliance with ISO 9001 will only attain international credibility where an independent (third-party) certification body who can substantiate the claim has been used.

4.2 **Annex SL**

4.2.1 The 2015 ISO standard has adopted the format and terminology of Annex SL, which will, in the future, apply to all ISO management system standards. Annex SL was developed by ISO to ensure all future ISO management system standards share a common format, irrespective of the specific discipline to which they relate. It details a high-level structure, identical core text, and common terms and definitions. Although some requirements of ISO 9001:2008 (ISO, 2008) are essentially unchanged, these are found under a new clause/subclause heading in ISO 9001:2015. The unification of core sections of ISO standards will enhance the integration of different management systems (ISO 9001, ISO 14001, etc.).

4.2.2 The core sections are as follows, and the specific requirements of each management standard are articulated within these sections:

- Scope
- Normative references
- Terms and definitions
- Context of the organization
- Leadership
- Planning
- Support
- Operation
- Performance evaluation
- Improvement

4.2.3 It has been stated within the QM community that the changes resulting from the adoption of Annex SL will have the greatest impact on quality professionals (that is, those developing and implementing a QMS and those auditing a QMS). However, a primary objective of this Guide is to provide clarity of the intent for each clause and appropriate resources to assist in the development and implementation of a QMS.

4.2.4 The resources provided in the appendices below include tools and processes developed from extensive practical and successful experience in developing and implementing a QMS within an ISO 9001:2015 framework. Importantly, this experience includes the achievement

of certification of compliance to ISO 9001:2015 through an internationally recognized conformity assessment/certification body that is recognized globally by over 50 accreditation bodies such as, for example, the United Kingdom Accreditation Service.

4.3 Process approach – the plan, do, check, act cycle

4.3.1 Fundamental to ISO 9001:2015, and its predecessors, is a process approach that has been highlighted as one of the principles of QM. The plan, do, check, act (PDCA) cycle provides a methodology to assist in the development and implementation of this approach.

4.3.2 The PDCA cycle is an iterative four-step management process typically used in organizations that implement QM. It can be used to coordinate the efforts of WMO programmes and Member NMHSs to continually improve work processes. It emphasizes and demonstrates that improvement programmes must start with careful planning, must result in effective action and must move on again to careful planning in a continuous cycle. Figure 2 illustrates this process.

4.3.3 The development of a QMS within the ISO 9001:2015 framework will enable WMO programmes and Member NMHSs to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate QMSs with the requirements of other management system standards. These PDCA cycles can be applied to many levels within an organization and its activities.

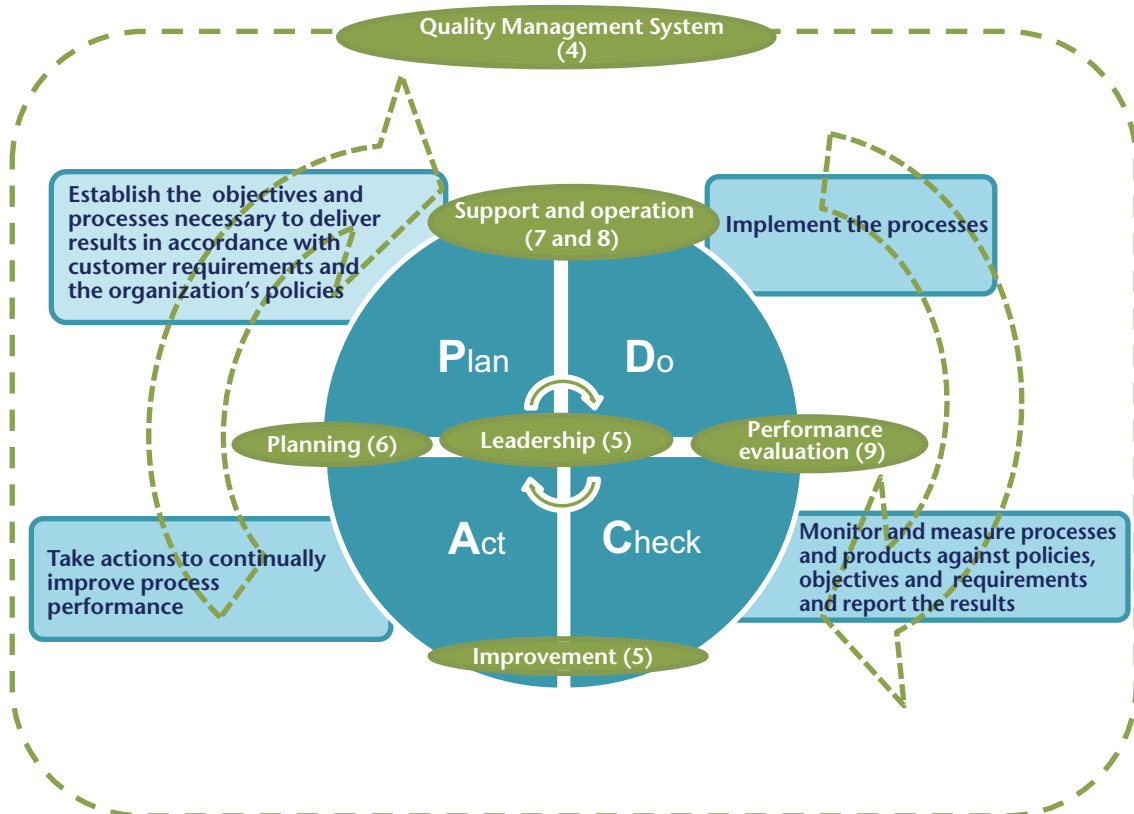


Figure 2. The PDCA cycle

4.4 **Risk-based thinking**

4.4.1 In a departure from its predecessor ISO 9001:2008, references to preventive action in ISO 9001:2015 have been removed. However, the core activity of identifying and addressing potential risks to the organization still remains. WMO programmes and Member NMHSs must be able to demonstrate that they have identified, considered and taken action (as appropriate) to mitigate any risks and capitalized (as appropriate) on any opportunities that may affect their organization. The approach to risk must be proportionate to the consequences, should the risk be realized. A practical approach is provided in the appendices to this Guide, especially Appendix 9, and includes looking at risks, for example, from operational, financial and legal perspectives.

4.5 **Explanatory notes**

4.5.1 Table 1 provides explanatory notes and insights into the intent of standard ISO 9001 on a clause-by-clause basis. It is imperative that users of this Guide read the table in conjunction with standard ISO 9001:2015, to ensure a full understanding and appreciation of each clause.

Note: Only the clause reference number and main heading are provided. The actual contents of the clause and any subclauses must be accessed via the ISO 9001:2015 standard.

Table 1. Explanatory notes for clauses from standard ISO 9001:2015

Clause 1 – Scope		
<i>Requirements</i>		
See ISO 9001:2015		
Clause 2 – Normative references		
<i>Requirements</i>		
See ISO 9001:2015		
Clause 3 – Terms and definitions		
<i>Requirements</i>		
See ISO 9000:2015		
Clause 4 – Context of the organization		
<i>Requirements</i>	<i>Guidance notes</i>	<i>Hints and resources</i>
4.1 Understanding the organization and its context	<p>There are many internal and external issues that affect, or have the potential to affect, the QMS. It is imperative these are identified so that there is clear understanding and appreciation of the operating environment. These perspectives are clearly articulated in the standard, and include technological, legal, market, economic and cultural issues.</p> <p>Notes 1 and 2 of the clause provide a broad framework within which to identify and assess the context.</p> <p>Understanding the context and formally addressing identified issues will help to ensure ongoing viability and credibility of the QMS.</p>	<p>The environmental scanning tool, which is broadly based on the traditional strengths, weaknesses, opportunities and threats (SWOT) analysis, provided in Appendix 1 to this Guide should be used. It is important that each step of the tool is followed, in particular, to ensure the issues identified are addressed as part of the planning process and that any risks identified have a formal risk mitigation strategy.</p> <p>The environmental scan will assist in determining the QMS scope as required under clause 4.3.</p> <p>The environmental scan and follow-up actions will also provide clear evidence of a comprehensive process undertaken to understand and react to the context within which the organization operates.</p>
4.2 Understanding the needs and expectations of interested parties	<p>Interested parties are stakeholders – any individual or organization that can affect the QMS, or any individual or organization that the QMS can affect. In both cases, the effect can be negative as well as positive.</p> <p>It is important that any statutory or regulatory requirements associated with interested parties are identified and addressed by the organization, as appropriate.</p>	<p>The first task in meeting the requirements of this clause is to identify all the QMS stakeholders/ interested parties.</p> <p>A simple but comprehensive stakeholder analysis should be performed. A stakeholder analysis template is provided in Appendix 2.</p> <p>Stakeholder analysis will also provide useful information that will further underpin the requirements of clause 4.3 and subclauses 5.1.2 and 9.1.2.</p>

4.3 Determining the scope of the quality management system	<p>Definition of the scope is a key component of a QMS. It provides the boundaries as to what is within the scope when it comes to developing, implementing and auditing the QMS.</p> <p>The scope is usually meticulously articulated on the certification of compliance to ensure there is absolutely no confusion as to what sections and activities of the QMS are certified as being in compliance with ISO 9001:2015.</p>	<p>The environmental scanning (see Appendix 1) activity will provide useful input into defining the scope of the QMS.</p> <p>It must be ensured that there is no ambiguity in terms of the scope. There must be no circumstances under which a section/area outside the QMS scope can be interpreted or inferred to be covered by the certification.</p> <p>The scope can be changed, but in terms of certification, this should be done in close consultation with the conformity assessment/certification body. Any changes to the scope should be subject to the requirements under the standard and subject to audit by the conformity assessment/certification body who would confirm, or otherwise, the inclusion of the change under the certification.</p>
4.4 Quality management system and its processes	<p>It is imperative that the organization has established a demonstrable process-based QMS.</p> <p>In line with other clauses within the standard, the QMS will need to be maintained and monitored. This clause clearly articulates the high-level requirements for the design of a process-based management system, under subclause 4.4.1.</p>	<p>There is now a greater focus on the QMS processes and the associated documentation.</p> <p>The process matrix template in Appendix 3 provides a useful tool for identifying and addressing the requirements of this clause.</p> <p>It provides useful evidence for demonstrating the processes that underpin QMS activities.</p> <p>It is also a useful planning tool in terms of providing input into the requirements of other clauses including those associated with risk, planning, resources, and the monitoring and measuring of outputs of the QMS.</p> <p>The process matrix can be a useful artefact to present at audit.</p>
Clause 5 – Leadership		
<i>Requirements</i>	<i>Guidance notes</i>	<i>Hints and resources</i>

<p>5.1 Leadership and commitment</p> <p>5.1.1 General</p>	<p>Standard ISO 9000:2015, subclause 2.3.2.1, states that “Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization’s quality objectives.”</p> <p>Standard ISO 9000:2015, subclause 3.1.1, defines “top management” as a “person or group of people who directs and controls an organization at the highest level ... Top management has the power to delegate authority and provide resources within the organization.”</p> <p>Top management is expected to demonstrate leadership and commitment to the QMS and accountability for its ongoing sustainability. Top management must be able to clearly demonstrate practical involvement in leadership of the QMS.</p> <p>An often-used phrase in the QM community relevant to this clause is that the “video needs to be in sync with the audio”. That is, words alone will not suffice; they must be backed up with clear decisive actions that demonstrate meaningful support for the QMS.</p>	<p>It is appreciated that this may present a daunting task for the QM professionals developing and implementing a QMS for their organization. However, there are some effective activities that can involve top management and which enable it to provide some positive and practical inputs. Top management should be provided with a comprehensive briefing on QM that includes a broad overview of ISO 9001:2015.</p> <p>During the top management briefing, an in-depth explanation of roles and responsibilities under clause 5 should be provided, to ensure that management has a thorough understanding and appreciation of what is involved.</p> <p>Top management should be provided with a draft quality policy that can be modified as appropriate and endorsed. It is imperative that management fully understand and appreciate the requirements under clause 5.2. Appendix 4 provides examples of quality policies that may be useful for adapting to the QMS.</p> <p>It should be ensured that members of the top management chair the quality management review meetings (QMRMs). This provides useful insight into the grassroots processes and enables management to respond accordingly. It is imperative that management fully understands and appreciates the requirements under clause 9.3 and subclauses 9.3.2 and 9.3.3.</p> <p>The insight that top management receives during QMRMs will provide useful input into the QMS planning processes. See clause 6.</p> <p>It is absolutely critical that top management is well prepared for audits, both internal and external. This will ensure a successful audit result. The need for this cannot be emphasized enough.</p> <p>The QM professional who has responsibility for development and implementation should provide a coaching/mentor role for top management. A good starting point is to provide a comprehensive briefing on the audit process and give a sense of the questions that may be encountered. Appendix 5 provides a useful overview and examples of questions that may be asked regarding the role of top management in the QMS. These should be reviewed with top management, to ensure it is familiar with the context of each question.</p>
<p>5.1.2 Customer focus</p>	<p>Top management is now required to take the lead role in demonstrating QMS commitment to customers.</p> <p>In particular, customer requirements and statutory and regulatory requirements must be identified, understood and consistently addressed.</p> <p>Any potential risks that threaten continuity of services and products, and the level of customer satisfaction, should be mitigated.</p> <p>In addition, top management must also ensure the QMS remains focused on delivering conforming products and services, on meeting its statutory and regulatory obligations and on enhancing customer satisfaction.</p>	<p>This is not a one-off activity for top management but one that will underpin ongoing levels of customer satisfaction and continuous improvement.</p> <p>The key to addressing the requirements of this clause is identifying and meeting customer needs, and, wherever possible, exceeding their expectations.</p> <p>An excellent first step is formally identifying and documenting those needs so they can be monitored and measured. Appendix 6 provides a useful template for achieving this.</p> <p>The development and implementation of a documented, scheduled review of requirements process is a useful component of Appendix 6. It provides evidence to demonstrate how subclause 8.2.3 is being addressed.</p> <p>Establishing levels of customer satisfaction as per subclause 9.1.2 should be undertaken in conjunction with reviewing of customer requirements (see Appendix 7).</p> <p>Identifying and meeting the requirements not stated by the customer are often key elements to success. Taking the time to clearly identify customer needs is important and is underpinned by experience of working with the customer base. The positive results that can be obtained are well worth the effort.</p>

<p>5.2 Policy</p> <p>5.2.1 Establishing the quality policy</p>	<p>The quality policy is a key document of the QMS. Subparagraphs 5.2.1(a)–(d) set a clear framework for the policy and should be adhered to.</p> <p>It is important to note that there is emphasis on the quality policy being appropriate to the organizational context and strategic direction, as well as to the purpose of the QMS.</p> <p>The quality policy will also provide a broad framework for setting QMS objectives.</p> <p>Top management needs to lead the establishment, creation, review and ongoing maintenance of a quality policy that is relevant to activities.</p>	<p>As stated previously, top management should be provided with a draft quality policy that can be reviewed as appropriate, and it should be ensured that it fully understands and appreciates the requirements under this clause. Appendix 4 provides examples of quality policies that may be useful for adapting to the QMS.</p> <p>The QMS context and strategic direction should have already been established in clause 4.1, and it should therefore be readily articulated into the quality policy.</p> <p>Remember any change in strategic direction will require a review and an amendment to the quality policy, as appropriate.</p> <p>Review the quality policy on a scheduled basis (yearly) for its continued suitability and viability.</p>
<p>5.2.2 Communicating the quality policy</p>	<p>The quality policy must now be readily available to stakeholders and the QMS, and it will need to be carefully considered how this is done.</p>	<p>A powerful way to communicate the quality policy is to post it on the website. It is also essential that top management’s verbal commitment in meetings, internal conferences and so forth is clearly articulated.</p> <p>There is also merit in validating, during QMRMs, that any proposed changes to the QMS still align with the quality policy. If not, a review of the policy and the proposed changes should be undertaken and documented as part of the minutes of QMRMs.</p>
<p>5.3 Organizational roles, responsibilities and authorities</p>	<p>Many avoidable errors and much wasted time will occur in a QMS when employees are not clear about what they are responsible for and what decision-making power they have. Top management must ensure that responsibilities and authorities are defined and communicated within the QMS.</p> <p>Responsibilities and authorities of each employee should be clearly defined and be available to all staff. Although there is no longer a requirement for a QM representative, there is a new requirement for top management to ensure that someone is tasked with preserving the integrity of the QMS while planning and undergoing change. See subclause 5.3(e).</p>	<p>Inevitably, some QMSs do not regularly review and update job descriptions and associated duty statements. Scheduled reviews of job descriptions should be clearly articulated, in particular, when a position is advertised as a vacancy.</p> <p>A traditional organization chart is still an excellent tool for illustrating reporting lines, but it is imperative that it is kept up to date, on both hard and soft copy.</p> <p>Auditors frequently use the organization chart as a starting point for an audit because it should clearly illustrate the scope of the QMS.</p> <p>A focus of ISO 9001:2015 has been to integrate QM activities across the QMS through the removal of the management representative role requirement. These activities include ensuring QMS processes are established and maintained, reporting of QMS performance and focusing on customer requirements. In reality, mature QMSs have already integrated these activities as part of their business as usual.</p> <p>Providing a QM duty in job descriptions and duty statements has proven to be an effective way of achieving this. Appendix 8 provides some examples of how this can be performed for various levels within an organization.</p> <p>It is no longer a requirement of ISO 9001:2015 to have a QM representative. However, experience has clearly demonstrated that as a QMS matures, this is not the case. A QM professional is required to ensure the ongoing sustainability, viability and integrity of the QMS. In fact, subclause 5.3(e) highlights the need to ensure this occurs as part of planning and undergoing change (see section 5.3 of this Guide).</p>
<p>Clause 6 – Planning</p>		

<i>Requirements</i>	<i>Guidance notes</i>	<i>Hints and resources</i>
6.1 Actions to address risks and opportunities	<p>This clause reflects a key outcome from clause 4.1 when establishing the context of the QMS. Determining the risks and opportunities flows directly out of that process. Addressing the risks (in particular) and opportunities will ensure the QMS achieves its planned objectives.</p> <p>Note 1 of this clause provides options for mitigating risks, and note 2 provides methods for capturing opportunities and potential outcomes.</p> <p>Subclause 6.1.2 highlights the need for a planned approach, that the associated actions should be integrated into the QMS and that their effectiveness should be evaluated.</p>	<p>Although developing and implementing a formal risk management process is not a requirement, due consideration should be given to using ISO 31000:2009, Risk Management – Principles and Guidelines (ISO, 2009b), to underpin how risk is addressed.</p> <p>It is therefore strongly encouraged that identification and management of risks be formally undertaken and documented.</p> <p>Risk management can be defined as the identification, assessment and prioritization of risks. However, the most important aspect is to mitigate the risks using appropriate resources to monitor and minimize any potential impacts on the QMS.</p> <p>Appendix 9 provides a risk matrix with brief notes that may be useful in the management of the QMS risk profile. It is strongly recommended that formal training in risk management be undertaken.</p> <p>There can be a tendency to only focus on risk, and in doing so, miss the possibility to capitalize on identified opportunities. The register in Appendix 22 helps to ensure opportunities that are identified – especially as part of the environmental scanning process – are captured and, where possible, capitalized on. The register is comprehensive and has proven to be a useful and practical QM tool.</p>
6.2 Quality objectives and planning to achieve them	<p>This clause requires QMSs to set quality objectives for relevant functions, levels and processes within the organization.</p> <p>It is important to ensure that the quality objectives and associated key performance indicators (KPIs) are consistent with the quality policy (see clause 5.2), are relevant to the products and services, and demonstrate they are meeting or exceeding customer expectations.</p> <p>Subclauses 6.2.1 and 6.2.2 provide clear requirements in terms of the quality objectives and how to achieve them.</p> <p>It should also be noted that any externally provided processes, products and services may also require quality objectives (see subclause 8.4.1).</p>	<p>Organizational planning activities affect several areas within the QMS, and it is imperative to ensure this activity is comprehensively undertaken and well documented.</p> <p>It is important that QMS objectives are validated against any higher level strategic and/or corporate planning objectives to ensure their alignment with the broad QMS direction.</p> <p>When developing KPIs, it is important that they are realistic and meaningful in terms of providing useful insight into the performance of the QMS in meeting its identified objectives. For example, a KPI that states “the issue of 100 000 forecasts” is meaningless in terms of the quality and usefulness of those forecasts. More-informative KPIs in terms of performance would be, for example, “95% of forecasts issued at the scheduled time” or “95% of forecasts verified as accurate”.</p> <p>It is important to ensure KPIs are meaningful to all key stakeholders including the customer(s), top management, supervisors and the staff who actually produce the products and services. Using input from the staff who produce the products and services involved in determining KPIs is a sound management strategy that will have significant benefits in terms of buying in to a QM approach.</p> <p>The environmental scan (Appendix 1) and the outcomes from that process, combined with the process matrix (Appendix 3), provide a useful source and a good starting point for formulating quality objectives.</p>
6.3 Planning of changes	<p>When changes to the QMS are required, they must be performed in a planned and systematic manner.</p>	<p>One of the most important aspects of this clause is documenting planned changes. It should be noted that under subclause 9.3.2, there is a requirement that changes are an important input. Having any changes that may affect the QMS as a standing agenda item of QMRMs is a good way of ensuring this happens.</p>

	<p>Due consideration should be given to what the change is trying to achieve and any potential consequences (positive or negative), while ensuring that the overall integrity of the QMS is maintained.</p> <p>Other issues that need to be taken into account include whether there are sufficient resources available and the potential impact on any roles and responsibilities.</p> <p>Documented information needs to be retained relating to planned changes and their potential impact on the QMS.</p>	
Clause 7 – Resources		
<i>Requirements</i>	<i>Guidance notes</i>	<i>Hints and resources</i>
7.1 Resources 7.1.1 General	<p>This clause focuses on the requirement for the QMS to determine the resources (internal and external) required for implementation, maintenance and continuous improvement.</p> <p>The subclauses of 7.1 have specific focuses on people (7.1.2), infrastructure (7.1.3), environment for the operation of processes (7.1.4), monitoring and measuring resources (7.1.5) and organizational knowledge (7.1.6).</p>	<p>When determining resources, it is important to ensure they are aligned with the quality objectives endorsed by top management.</p> <p>The importance of obtaining the appropriate level of resources to support the ongoing viability and improvement of the QMS should be emphasized.</p> <p>The importance of obtaining the appropriate level of resources to either achieve or maintain the certification of compliance to ISO 9001:2015 should also be emphasized.</p>
7.1.2 People	<p>This subclause focuses on ensuring the appropriate staff is available for effective operation of the QMS.</p> <p>This also includes ensuring there is adequate staff to meet customer and applicable statutory and regulatory requirements.</p>	<p>Meeting identified customer needs and ensuring a high level of customer satisfaction (subclause 9.1.2) is a significant driver for ensuring levels of appropriately qualified/competent staff.</p> <p>Ensuring applicable national and international statutory and regulatory requirements are met is another significant driver for having correct levels of appropriately qualified/competent staff.</p>
7.1.3 Infrastructure	<p>The requirements for this subclause focus on identifying, providing and maintaining the infrastructure resources to ensure processes operate effectively.</p> <p>Examples are provided on what is considered for inclusion as infrastructure.</p>	<p>Lack of appropriate infrastructure can significantly undermine the viability of the QMS.</p> <p>It is recommended that any issues or concerns relating to infrastructure be identified via means that include section/staff meetings and other organizational forums, including internal and external audits. If they have been identified and there is a well-documented and appropriately resourced plan in place, it should not be a major issue. In fact, it demonstrates that the QMS is working.</p> <p>It must be remembered that the QMS is a dynamic real-life organizational entity within which things can and do go wrong. Therefore, things cannot be perfect all of the time – even during an audit.</p>

7.1.4 Environment for the operation of processes	<p>This subclause focuses on the organization's need to "determine, provide and maintain" a suitable environment for the operation of processes.</p> <p>This subclause notes that a suitable environment can be a combination of physical, social, psychological, environmental and other factors, including temperature, cleanliness, prevention of staff burn out, etc.</p>	<p>The comments made above under subclause 7.1.3 apply just as readily to this subclause.</p> <p>Most importantly, a documented process that identifies potential or current issues and articulates a procedure to rectify any issues as quickly as possible should be in place.</p> <p>The internal audit process may identify issues, as will a work, health and safety culture embedded within the QMS.</p>
7.1.5 Monitoring and measuring resources 7.1.5.1 General	<p>This subclause focuses on monitoring and measuring activities to demonstrate that products and services conform to requirements.</p> <p>There must be an appropriate level of resourcing to assure that the monitoring and measuring is suitable for the activity and will provide valid and reliable results.</p> <p>It is also important to ensure that the resources needed for monitoring or measuring are maintained to a standard that is fit for purpose.</p> <p>Appropriate documented information (records) must be maintained.</p>	<p>It should be ensured that all monitoring and measuring equipment documentation is up to date and readily available.</p> <p>It should also be ensured that all monitoring and measuring records are kept up to date and are readily available to appropriate staff.</p> <p>It should be ensured that the results of monitoring and measuring are periodically reviewed on a scheduled basis and that there is a documented process in place to address any identified issues.</p> <p>All of the above apply to both external and internal providers.</p>
7.1.5.2 Measurement traceability	<p>This subclause focuses on providing confidence that measuring equipment has been calibrated against international or national measurement standards.</p> <p>There must also be documented traceability that clearly articulates when and how equipment has been calibrated and to what standard. The "when" can be at specified intervals or prior to use.</p> <p>The need to protect measuring equipment from damage and to ensure its ongoing integrity is highlighted.</p> <p>This subclause states that if national or international standards do not exist, then the organization must have documented information detailing the underlying basis used for the calibration or verification of the measuring instrument.</p> <p>It also states the action necessary to be taken if equipment has been found unfit for purpose.</p>	<p>Comprehensive and well-maintained documented records are key to meeting the requirements of this subclause.</p>

7.1.6 Organizational knowledge	<p>The focus of this subclause is to ensure the organization captures and preserves knowledge, which underpins processes and ensures the quality of products and services. It emphasizes the need to ensure that the knowledge is contemporary in that it reflects current needs and trends; if not, the additional knowledge should be obtained.</p> <p>Two notes associated with the subclause provide clarification on what organizational knowledge is and that it can be based on internal and external sources.</p>	<p>The ongoing need to reassess and establish the needs of the organization is closely linked to other requirements of ISO 9001:2015. Clause 4.1, for example, addresses the context of the organization within the environment in which it operates. As that environment changes, it is essential to ensure the appropriate organizational knowledge is maintained or acquired.</p> <p>Using the environmental scanning tool (Appendix 1) on a scheduled basis (for example, annually just prior to the organization's planning process) provides an excellent opportunity to reassess the level of organizational knowledge.</p> <p>Another opportunity to establish or reassess the organizational knowledge is when establishing customer needs. See subclauses 5.1.2, 8.2.2, 8.3.6 and 9.1.2.</p> <p>The generic handover/takeover procedure in Appendix 21 is a useful organizational knowledge tool, as are up-to-date job descriptions, organizational charts, standard operating procedures (SOPs), internal web pages, refresher training and a sound internal communications protocol. Clause 8.4 provides the organization with the opportunity to consider knowledge required "in-house" to influence and control external processes. This may require appropriate training of specific staff.</p>
7.2 Competence	<p>Establishing and documenting levels of competence is a key clause and is fundamental to the organization.</p> <p>Once determined, the organization must then ensure the staff is competent through appropriate education, training or experience. If competence needs to be acquired, the organization must take the appropriate action to do so. A follow-up evaluation of the effectiveness of the action taken needs to be documented.</p> <p>Documented evidence of competence is also a requirement.</p> <p>It is important to note that that "people doing work under its control" will include contractors and the staff of external providers to which work has been outsourced. Subclause 8.4.3 also makes specific reference to this under subparagraph (c).</p>	<p>Standard ISO 9000:2015 defines competency as the ability to apply knowledge and skills to achieve intended results.</p> <p>After establishing the level of competence required with each position in the QMS, there is merit in undertaking a simple competence needs analysis for each staff member. This will provide the QMS with a comprehensive overview of the competence profile and provide excellent evidence for audits.</p> <p>Appendix 10 provides a simple template to adapt for this purpose.</p> <p>Once the required level of competence is identified, the job description documentation for each position should be reviewed and amended as appropriate, to reflect the requirements.</p> <p>There is also merit in establishing a competence review period (for example, every 3 years).</p> <p>WMO has some existing competence frameworks, and details of these may be accessed via the WMO competencies web page (http://www.wmo.int/pages/prog/dra/etrp/competencies.php).</p>
7.3 Awareness	<p>Awareness has been elevated to a clause in its own right. It should also be noted that as with clause 7.2, it applies to all "persons doing work under the QMS's control". Subparagraphs (a)–(d) of the clause state employees shall be aware of quality policy, the quality objectives, their contribution to the effectiveness of the QMS and the implication of not conforming.</p>	<p>The requirements of this clause mean that it is incumbent for the QMS to ensure "all persons doing work under it" are fully briefed on the QMS.</p>

		<p>It would be prudent to have these as key components of the QMS induction process for new staff (including contractors). It would also be practical to document the induction and ensure it is signed off by inductees for several reasons, including evidence for an auditor.</p> <p>Clearly, this also requires a healthy degree of common sense in terms of the level of engagement and the potential impact that contracted staff may have on the QMS.</p> <p>The generic handover/takeover procedure given in Appendix 21 is a valuable tool to utilize here.</p>
7.4 Communication	<p>This clause focuses on all internal and external communication relating to the organization's QMS.</p> <p>The clause clearly articulates, in subparagraphs (a)–(e), specific requirements for internal and external communication.</p> <p>It should be noted that there is a customer-specific communication subclause (8.2.1), which also needs to be addressed.</p>	<p>The development of a communications plan for the QMS will greatly assist in meeting the requirements of this clause.</p> <p>Internal/ external communication lines can easily be identified if a mature management system has been established.</p> <p>Additional information for internal communication can also be found in service level agreements (SLAs) between departments/programmes.</p> <p>External communication should include communication based on contracts and information about status of the service (on the website).</p> <p>An example of a diagrammatic communications plan is provided in Appendix 11 as a template for adaption if required.</p>
7.5 Documented information 7.5.1 General	<p>Subclause 7.5.1 includes all documented information identified as a requirement of ISO 9001:2015 and that required for the effective operation of the QMS.</p> <p>The subclause notes that the extent of documented information can differ between QMSs due to their size, complexity, products and services, and competency of staff.</p>	<p>There is no longer an explicit requirement for a quality manual as per ISO 9001:2008 requirements. However, experience has shown that operators of mature QMSs have expressed a strong desire to maintain the quality manual, because it is an ideal induction tool and provides a road map as to how the QMS works. A procedure for documenting information would also be beneficial.</p> <p>Reviewing and, as appropriate, amending a current 2008 quality manual to reflect the 2015 requirements has the benefit of giving the reviewer an enhanced understanding and appreciation of the new standard.</p> <p>In the early stages of development and implementation, QMSs are opting for specific dedicated QM web pages that take the place of a quality manual and have proven to be effective.</p> <p>It must be remembered that any web-based documented information, in particular operational processes, need to be secure. The development of a detailed documented process that clearly delineates lines of authority for changing processes (particularly online) and notifying stakeholders is imperative for the QMS.</p>
7.5.2 Creating and updating	<p>This subclause focuses on ensuring documented information that is created or updated is appropriately identified, described, reviewed and approved.</p> <p>Subparagraphs (a)–(c) clearly articulate the requirements.</p>	<p>The use of document control panels and the use of headers and footers are ideal for document identification.</p> <p>Online QM pages also require identification of and information on the currency of the document and updates. These elements should be included in any QM web-page design</p>

7.5.3 Control of documented information	The subparagraphs under subclauses 7.5.3.1 and 7.5.3.2 clearly articulate the requirements in terms of control of documentation. It is also stated that documented information from external sources that is used as part of the planning and operation of the QMS must be identified and controlled.	Auditors will focus on the permissions to access documentation and, more importantly, who has the authority to change or approve changes to documentation. Who has the authority on changes and approvals needs to be clearly documented and reflected in a document control panel. This also includes a check of the documented information to ensure it is up to date and protected against improper use. Maintaining the integrity of documentation extends to web-based documentation such as wiki pages. Therefore, the control of documented information must be reflected in the web-based environment, in particular, for operational documentation such as SOPs.
Clause 8 – Operation		
<i>Requirements</i>	<i>Guidance notes</i>	<i>Hints and resources</i>
8.1 Operational planning and control	This clause articulates the requirements for the planning, implementation and control of processes. The clause is strongly linked to the requirements addressed in several clauses, in particular, clauses 4.4, 6 and 8.4.	The information obtained from the environmental scanning tool (Appendix 1) can provide useful input for addressing this clause. The suggested process matrix in Appendix 3 can provide useful input into how the requirements are being addressed. It should be ensured that any identified risks are reflected in the suggested risk register (see Appendix 9). Control of externally provided processes, products and services has the potential to present some unique challenges, which are addressed under clause 8.4.
8.2 Requirements for products and services 8.2.1 Customer communication	Subclause 8.2.1 focuses on QMS communication with customers. There is a clear link between subclause 5.1.2 and clause 7.4. The subparagraphs of subclause 8.2.1 clearly articulate the requirements for customer communication.	Meeting customer identified needs is a key objective and it is therefore imperative to clearly identify and understand the needs of the QMS customer base. For example, customers can also be found within an organization, and there are different ways of accessing information on products and services. Web-based provision of products and services is common for aviation. It is highly recommended that, at the very least, a simple customer register be developed that identifies customer names, community sectors they are from (for example, aviation, marine, agricultural or the general public), products and services the QMS provides to the customers and frequency with which the needs of the customer are reviewed. It is important for all staff involved in the provision of products and services to have an understanding of the potential impact (positive and negative) on customer operations. Appendix 6 provides a simple template for this purpose. It is appreciated that some QMSs may develop comprehensive databases, and the template is only presented as a starting point for consideration. A key customer communication strategy is a scheduled review of the current products and services provided. It is strongly recommended that a review schedule be developed and documented. Apart from being a useful planning tool, it has the additional benefit of providing evidence for audit purposes. There is considerable value in integrating the requirements under subclause 8.2.1 into the communications plan (Appendix 11).

8.2.2 Determining the requirements for products and services	<p>This subclause focuses on determining the requirements for the customer products and services. The subparagraphs clearly articulate the requirements.</p> <p>Identification of any applicable statutory and regulatory requirements in terms of the products and services being offered is crucial. Ensuring the QMS can meet the claims that it makes on the products and services it intends to offer is vital to the ongoing credibility of the QMS.</p>	<p>The development of proposed customer records (see Appendix 6) offers the ideal opportunity to address the requirements of this subclause.</p>
8.2.3 Review of the requirements for products and services	<p>This subclause focuses on reviewing the requirements for products and services. The subparagraphs under subclauses 8.2.3.1 and 8.2.3.2 clearly articulate the requirements. The requirements state the QMS needs to be reviewed to ensure it can provide the products and services prior to committing to them. Subparagraph (b) highlights that consideration should be given to any requirements not expressly stated by the customer but which may be known to be necessary for the product or service to be fit for purpose and meet customer needs.</p> <p>It is important that all reviews of customer requirements are documented and retained and that any changed requirements to products and services are communicated to relevant stakeholders.</p>	<p>As stated previously, a documented scheduled review of product and services requirements for customers is strongly recommended and can be useful.</p> <p>The development of proposed customer records (see Appendix 6) and the subsequent interaction with the customer offer the ideal opportunity to address the requirements of this subclause. It is appreciated that identifying the customer when the general public is the customer can be challenging. However, innovative approaches such as face-to-face meetings, specific focus groups and user groups provide invaluable feedback and input for addressing the requirements of this subclause.</p> <p>Useful feedback can also be obtained from online surveys, which can be developed for the general public/community feedback or for specific user groups. It is strongly recommended that considerable care be taken in developing survey tools to ensure they provide the level of feedback that is being sought.</p>
8.2.4 Changes to requirements for products and services	<p>This subclause focuses on the relevant action being taken when requirements are changed to ensure key stakeholders are informed.</p>	<p>The advising, to key stakeholders, of changes in requirements, in particular staff who provide the products and services, has the potential to be contentious.</p> <p>For example, within a 24-hour shift-work environment, managers will not always have the opportunity to pass on information relating to any operational changes to products and services face to face. Email advice is one method that is frequently used in today's operational environment. The "request a delivery receipt" and/or "request a read receipt" email tracking are options. However, neither guarantees that the recipient, although having received the email, has read and understood the changes, which, in the operational environment, could be critical.</p>

		<p>An incident/accident resulting from the failure to make a significant operational change can have serious consequences – especially if the staff member who issued the product had received notification by email. It would be difficult for the manager/supervisor who advised of the change to confirm the change required was understood by the staff member who issued the product. It could be argued that receiving the email and understanding the required changes or seeking clarification is an expectation as part of the professionalism associated with issuing a product. However, human factors need to be taken into consideration, and management/supervisory staff and operational staff are potentially exposed, especially if there is an enquiry or investigation related to an incident.</p> <p>It is highly recommended that due consideration be given to how this issue can be addressed. The potential incident scenario (referred to above) can be addressed through the use of a reading log. The manager/supervisor sends an email advising of a change to a product or service. The shift-work staff members are given a specified number of days to sign a simple reading log which acknowledges that they have read and understood the required change(s). Shift supervisors are required to check on a shift-by-shift basis the status of the reading log and that any staff on duty have read and signed it.</p> <p>It is strongly recommended to announce changes well in advance, to give employees enough time to prepare. Sometimes, just informing via email is not sufficient, and a training session may well be the most appropriate way.</p> <p>The above provide effective key procedures that satisfy audit requirements under this clause.</p>
8.3 Design and development of products and services 8.1.1 General	This clause focuses on the QMS establishing, implementing and maintaining a design and development process that is appropriate to the provision of products and services.	<p>It is appreciated that the design and development of products within the environment of WMO and Member NMHSs can be different to that of other QMSs. However, this clause and its associated subclauses provide a useful framework for development and design activities. However, a QMS that develops specific templates to meet needs will need to ensure that all of the requirements of this clause (in its totality) are included.</p> <p>To address the requirements, it is strongly recommended that a project template approach be adopted. There are commercial “off-the-shelf” software packages available (for example, PRINCE2) that can be readily adapted for this purpose. A project control should be established, and the verification and validation phases clearly highlighted.</p> <p>Validation follows verification to prove that the design of a product or service has worked in practice. The greater the risk associated with the product, the more extensive this validation should be.</p> <p>The role of this Guide is not to provide methodologies for validation and verification. However, it is strongly encouraged that contemporary validation/verification methodologies be adopted to assist in meeting the requirements of these clauses. The WMO website is a useful source of information relating to verification.</p> <p>Appendix 12 provides some basic templates that can be easily adapted to assist in meeting and documenting the requirements of this clause and its subclauses.</p>
8.3.2 Design and development planning	The subparagraphs of this subclause clearly articulate the requirements for design and develop planning.	
8.3.3 Design and development inputs	The subparagraphs of this subclause clearly articulate the requirements for inputs into design and development.	
8.3.4 Design and development controls	The subparagraphs of this subclause clearly articulate the requirements for controls for design and development.	
8.3.5 Design and development outputs	The subparagraphs of this subclause clearly articulate the requirements for outputs from design and development	
8.3.6 Design and development changes	The subparagraphs of this subclause clearly articulate the requirements for design and develop changes.	

<p>8.4 Control of externally provided processes, products and services</p> <p>8.4.1 General</p>	<p>This clause focuses on ensuring that externally provided processes, products or services meet the QMS requirements.</p> <p>It places a clear requirement on the QMS to ensure that externally provided processes, products or services meet QMS requirements. It is also a requirement to determine the criteria to evaluate and select external providers and to monitor and evaluate their performance.</p> <p>The QMS must retain documented information as evidence of external provider evaluations.</p>	<p>The requirements under this clause demand a structured approach as to how they are addressed. To facilitate this, an external providers register has been developed (see Appendix 13).</p> <p>In view of its comprehensive nature, the register offers an ideal opportunity to address the requirements of this clause. It is a useful exercise, and once it has been completed, ongoing maintenance will only require a simple periodic review.</p> <p>The register has proven to be a useful tool for highlighting the awareness and understanding of the QMS operations/activities and it also provides an excellent foundation for building a useful record of information to present as audit evidence.</p>
<p>8.4.2 Type and extent of control</p>	<p>This subclause focuses on the QMS determining the type and extent of controls applied to external providers.</p> <p>The subparagraphs of subclause 8.4.2 clearly articulate the requirements for the type and extent of control applied.</p>	<p>An external providers register (see Appendix 13) can play a key role in ensuring these requirements are addressed and appropriately documented.</p> <p>Control mechanisms may include a check of products at delivery, site acceptance tests, supplier audits, etc. If supplier audits are required, this should be in the contracts with the suppliers.</p> <p>There is a section within the external providers register that focuses on controls.</p>
<p>8.4.3 Information for external providers</p>	<p>This subclause and the associated subparagraphs clearly articulate the requirements for information that the QMS is required to communicate to external providers.</p>	<p>The external providers register (Appendix 13) can play a key role in ensuring the requirements are addressed and appropriately documented.</p> <p>There is a section within the external providers register that focuses on the information that is to be communicated to the external providers. (It is located under the “external information” tab.)</p> <p>It would be useful to give consideration to developing an SLA that clearly defines the level of service expected from the provider, in particular, aspects of the service including quality and availability.</p>
<p>8.5 Production and service provision</p> <p>8.5.1 Control of production and service provision</p>	<p>Subclause 8.5.1 requires the QMS to control the manner in which products are produced and the services provided. The subparagraphs clearly articulate the requirements for control of production and service provision.</p> <p>It should be noted that this clause is closely linked to some other clauses (and their subclauses), including clauses 5.2, 7.1, 7.2, 7.4 and 8.2.</p>	<p>The information obtained in addressing the requirements of other clauses and their subclauses will provide useful input into addressing the requirements of this clause.</p> <p>In particular, completion of the customer records template (Appendix 6) and the external providers register (Appendix 13) will provide excellent input for addressing the requirements of this clause and evidence for audit purposes.</p>

8.5.2 Identification and traceability	<p>The QMS must have a process in place for the identification and traceability of outputs, to enable the demonstration of conformity to requirements.</p> <p>There is a requirement for the QMS to be able to identify the status of outputs in terms of the monitoring and measurement requirements at all stages of production that it has set.</p>	<p>The majority of organizations within the WMO community will be able to clearly demonstrate meeting the requirements of this subclause in terms of their operational products that have a set format. This is usually possible by the date and time of the dissemination of the product. In aviation, for oral flight briefings via telephone, a recording system will help to meet the requirements.</p> <p>Common practice now also includes a unique identification number/code for each product disseminated. Once a product is disseminated and archived, it should be relatively easy to trace. As a first step to addressing the requirements of this subclause, it is strongly recommended that all operational products are reviewed to ensure ease of identification and traceability. If any products are not easily identified or traced, steps should be initiated to remedy the situation.</p> <p>It is highly recommended that an automatic/electronic solution be found to enhance identification and traceability. This could involve the use of unique document control numbers, header and footer information or formatting of products to include unique identification numbers.</p>
8.5.3 Property belonging to customers or external providers	<p>This subclause focuses on the QMS responsibilities in terms of taking care of property owned by customers and or external providers.</p> <p>The QMS must ensure that any customer or external provider property provided for QMS use is identified, verified, protected and safeguarded against loss or damage.</p>	<p>Although this subclause is relatively straightforward, one aspect of customer and external provider property that should be taken into account is that of personal details including names, addresses and contact details.</p> <p>The need for confidentiality in terms of this information (property) should be a high priority of a QMS. If it is not appropriately protected, steps should be taken immediately to do so – for example, via password access for authorized staff.</p>
8.5.4 Preservation	<p>This subclause requires the QMS to safeguard its outputs during production and service provision to ensure conformity to requirements.</p> <p>The note to this subclause gives examples of preservation that provide guidance for addressing the requirements.</p>	<p>Clear, concise and well-documented practices and procedures are of significant assistance in meeting the requirements of this subclause.</p>
8.5.5 Post-delivery activities	<p>This subclause and its associated subparagraphs clearly articulate the requirements for post-delivery activities.</p>	<p>The customer records template is a useful tool for addressing the requirements of this clause. Information on post-delivery activities could be placed under the column Products/services received, any specific requirements, controls and post-delivery activities (see Appendix 6).</p>
8.5.6 Control of changes	<p>The focus of this subclause is the control of changes which will ensure that products or services continue to meet their specified requirements.</p> <p>A key element of the clause is the authorization of changes.</p>	<p>Authorization of changes is inevitably a “good trail” for auditors to follow. Therefore, it is essential to have well-documented procedures applicable to the authorization and control of changes.</p> <p>A change is always a phase of increased risk; therefore, it is recommended to conduct a risk analysis in advance.</p>
8.6 Release of products and services	<p>This clause requires the QMS to have well-documented practices and procedures applicable to the release of products and services.</p>	<p>It is essential to have well-documented practices and procedures that clearly delineate, as appropriate, the approval for the release of products.</p>

	The clause also has a strong link to subclause 8.5.2.	
8.7 Control of nonconforming outputs	<p>This clause focuses on identifying any products or services that do not conform to their intended requirements.</p> <p>Requirements also include the establishment of controls to ensure that non-conforming products are not delivered to the customer or that their unintended use is prevented.</p> <p>When non-conforming products are identified, the QMS is required to take appropriate action to rectify and document the non-conformance.</p>	<p>Regardless of how diligent a QMS is, processes do not always go according to plan and may result in non-conforming products. The QMS should have control mechanisms in place to ensure that any non-conforming products or services are identified and rectified.</p> <p>The key to this clause is the manner in which non-conformities are captured and recorded. It is recommended to keep a non-conformity log or something similar, which can help to identify recurring problems. In a shift-work environment, where a number of people occupy the same position, this is a vital QMS tool to inform staff of non-conforming products.</p> <p>Internal problems are usually found by employees as a result of real-time analysis, reported incidents (for example, an aviation occurrence management system within a safety management system (SMS)), inspections, maintenance activities or audits, whereas external problems are identified following post-delivery verification or customer feedback.</p> <p>It is strongly recommended to have a procedure that describes how non-conforming products are identified and captured, how they are rectified, who is responsible for the action, what action should be taken and what records are to be kept. A sample non-conformance procedure is provided in Appendix 14.</p> <p>Problems should not all be tackled in the same way. There may be a formal process for dealing with a major issue, but there should also be another process for tackling minor issues. The management of each work area, in close consultation with staff, should establish what is to be considered a major or minor problem, on the basis of established risk levels, and remedial actions should be defined and documented.</p>
Clause 9 – Performance evaluation		
<i>Requirements</i>	<i>Guidance notes</i>	<i>Hints and resources</i>
9.1 Monitoring, measurement, analysis and evaluation 9.1.1 General	<p>The focus of subclause 9.1.1 is determining what it needs to monitor and measure and how it is going to carry out these activities to ensure the results obtained are valid.</p> <p>The associated subparagraphs clearly articulate the requirements for the monitoring, measurement, analysis and evaluation of the QMS.</p>	<p>It is important to document and retain as evidence the results of the evaluation of the performance of the QMS.</p> <p>The objectives, and KPIs established under clause 6.2 will provide useful input into addressing this clause.</p>
9.1.2 Customer satisfaction	This subclause requires the QMS to put in place arrangements to monitor levels of customer satisfaction.	<p>The fundamental goal of any organization is to satisfy its stakeholders, primarily its customers. They are arguably the very reason for an organization's existence.</p> <p>Satisfied customers will help to ensure that the organization receives the appropriate level of funding. Therefore, it is important to gain a clear understanding of how satisfied they are with the products or services provided.</p> <p>Standard ISO 9001:2015 does not specify how a QMS can gain information on customer satisfaction, but it does provide examples of how this can be achieved (see note under subclause 9.1.2).</p>

		<p>However, it requires the monitoring of information relating to customer perceptions of the organization and whether their expectations have been met. The QMS should determine the best method(s) to do this.</p> <p>Surveys are commonly used for this purpose, but it is essential that the right questions are asked. Appendix 7 provides a generic template for a customer satisfaction survey that has been used successfully.</p> <p>Whatever the QMS decides to use to assess customer satisfaction, it should be ensured that the staff is made aware of the methods chosen and that these are applied consistently.</p>
9.1.3 Analysis and evaluation	<p>This subclause requires the QMS to analyse and evaluate data and information, obtained either internally or externally.</p> <p>Subparagraphs (a)–(g) provide a clear framework of what needs to be evaluated.</p>	<p>It is highly desirable to present the results of the analysis and evaluation in a concise format that can be easily understood by key stakeholders.</p> <p>Due consideration should also be given to reviewing this as part of the QM review process input agenda discussed under clause 9.3.</p> <p>The objectives and KPIs established under clause 6.2 to achieve them will provide useful input into addressing this clause.</p>
9.2 Internal audit	<p>Subclauses 9.2.1 and 9.2.2 of this clause and their associated subparagraphs provide a clear framework for conducting internal audits.</p>	<p>The audit process is the “glue” that holds the QMS together. It is a primary tool that a QMS can use to ensure it is operating effectively.</p> <p>From an audit perspective, key aspects of the QMS are processes and procedures. It is vital that they are established in close consultation with the staff that performs the associated activity. It is strongly recommended that the QMS selects appropriate techniques and suitable staff to perform internal audits. Unsuitable or poorly trained auditors can do significant damage to the QMS. As the QMS of an organization matures and its practices, procedures and techniques change, so should the QMS.</p> <p>The organization should select appropriately qualified staff that possess the personal character traits and attributes stated within ISO 19011:2011.</p> <p>The composition of the audit team itself is a key success factor. In general, conflict of interest should be avoided.</p> <p>Auditing is a way of ensuring that the QMS systems and processes are aligned and that new and improved techniques become normal practice.</p> <p>A good indication that a QMS is maturing is when employees welcome an internal audit of their activities.</p> <p>All audits should be conducted in a positive and non-threatening manner; otherwise, they will be a waste of time. Audits should help the QMS improve, and should not be conducted just to fulfil the requirements of the certification process.</p> <p>Standard ISO 9001:2015 does not specify the techniques to be used for conducting an internal audit. Unlike certification audits, internal audits are less formal and should be scheduled according to the QMS demands, priorities, available resources and risks associated with operations. To facilitate the internal audit process, it should be documented as guidance for all staff.</p> <p>A broad diagrammatic generic internal audit process is presented in Appendix 15. The internal audit does not assess all facets of the QMS at once, but uses samples of job descriptions, procedures, instructions, contracts (SLAs), policies, plans, organization charts, flow charts, etc., including the linkages among these documents.</p>

		<p>A flexible audit schedule is a critical component of the audit process, and should be developed prior to planning and budgeting activities.</p> <p>For example, 1–2 months prior to the development of the annual operational plan, the QMS should ensure that any significant issues identified during the audit are addressed as part of the planning process. The same applies to the budgeting process. Outcomes of an audit can highlight areas that require an injection of funds to rectify a specific issue.</p> <p>Internal audits should also be planned and carried out prior to external audits. However, they should not be performed only a few weeks before an external audit just to provide evidence to an auditor. They should be part of the day-to-day activities of the QMS.</p>
9.3 Management review	Subclause 9.3.1 requires reviews of the QMS to be conducted by top management at planned intervals to ensure ongoing suitability and effectiveness.	Top management involvement in QMRMs – preferably as chairperson – is fundamental to the success of the QMS. Therefore, it is imperative that top management is engaged early in the development and implementation of a QMS.
9.3.1. General		
9.3.2 Management review inputs	This subclause and its subparagraphs provide a clear framework for what must be considered at a QMRM.	<p>The subparagraphs of subclause 9.3.2 provide a standing agenda framework for QMRMs that should be adapted to meet the QMS.</p> <p>Appendix 16 provides a template that may be adapted to suit this need. It provides the QMS with structured evidence and helps to analyse and generate relevant input for management review.</p>
9.3.3 Management review outputs	This subclause provides specific outputs from management reviews.	It is highly recommended that the QMRM agenda is formulated to ensure the required outputs can be achieved.
Clause 10 – Improvement		
<i>Requirements</i>	<i>Guidance notes</i>	<i>Hints and resources</i>
10.1 General	This clause has a clear focus on improvement underpinned by meeting customer needs and enhancing customer satisfaction.	<p>Communicating with QMS customers is a crucial strategy in meeting the requirements of the clause.</p> <p>A key resource for this purpose is the customer records template (see Appendix 6), which can provide useful input into meeting the requirements of this clause.</p>

<p>10.2 Nonconformity and corrective action</p>	<p>This clause states the requirements for the occurrence of a non-conformity. The requirements also include action to prevent a similar non-conformity occurring. This is achieved via review and analysis to determine what caused it, and any actions to prevent it re-occurring in the future.</p>	<p>There is a clear link between clauses 8.7 and 10.2, and Appendix 14 provides a methodology for meeting the requirements of this clause. This clause requires that appropriate action be taken to address the effects of the problem. As per Appendix 14, this may require a simple correction by the duty officer or, in a major event, significant levels of resources. A risk analysis can help to determine the appropriate actions that need to be taken. Any ongoing risks should be recorded in the risk register (Appendix 9) and taken into account during future planning activities. Any non-conformities and subsequent actions to prevent the reoccurrence and the effectiveness of the corrective action(s), should be duly documented and retained. Therefore, due consideration should be given to the development of a non-conformities log or similar document.</p>
<p>10.3 Continual improvement</p>	<p>This clause requires the QMS to work continually to improve and specifically use the outputs from analysis and evaluation (see subclause 9.1.3) and from the management review process (see subclause 9.3.3).</p>	<p>This clause aims to ensure progress is being made to improve the effectiveness of the QMS. It raises questions such as:</p> <p>Are outputs better this year than last year? Is the use of resources being optimized? Is better use being made of system indicators such as audits, management review and data analysis? Overall, it is important that the QMS processes have identified any issues and that they have been documented and are in the process of being rectified – this is what happens every day in organizations around the world.</p>



KEY POINTS

1. It is important that WMO and Member NMHSs endeavour to adopt a simple and effective PDCA cycle approach in terms of processes. It is imperative that due consideration and appropriate resources be given to the identification and mitigation of risks. Managing risk is the responsibility of all staff, and it is a consideration that should be integrated into the overall QMS culture of WMO programmes and Member NMHSs.
2. The “Hints and resources” column in Table 1 and the appendices below provide a solid starting point on which to build a QMS. These tools have been developed and successfully applied to achieve certification of compliance with ISO 9001:2015.
3. Although not a requirement of the ISO standard, the templates in the appendices below provide a structured and consistent framework for addressing the requirements of the standard.
4. As an important additional benefit, the completed templates also provide a useful evidence base for the audit process.

5. STEPS FOR IMPLEMENTING A QUALITY MANAGEMENT SYSTEM

5.1 Implementation overview

5.1.1 Tables 2, 3 and 4 provide an overview of the steps that need to be taken to develop and implement a QMS. They can be used to provide a foundation tool at an initial meeting to discuss adoption of a QM approach to the delivery of products and services.

5.1.2 It is not possible to determine exactly how long it takes to implement a QMS, nor achieve certification of compliance with ISO 9001. Many factors can affect the time required to implement a QMS, including: the size of the organization, the extent to which the QMS will be introduced within the organization, whether QMS implementation is assisted by a consultant, the maturity of the QMS processes and documentation, the availability of resources, and the commitment of top management and staff.

5.1.3 Experience suggests that, with due regard to the above factors, 18–24 months is a realistic and achievable time frame for a small QMS or for specific sections of a large QMS. Small sections or units (approximately 20 staff) in a QMS could implement and achieve certification of compliance with ISO 9001 within a minimum of 18 months. That time period should also provide the opportunity to accumulate a body of evidence that clearly demonstrates, at audit, the successful implementation of the QMS.

5.1.4 It may also be advisable to adopt an incremental approach where a QMS is developed and implemented for different sections or programme areas. Success in these individual or smaller areas has the real potential to raise the confidence and level of staff buy-in, as well as making the task more manageable for the QM team overseeing the QMS implementation process.

Table 2. Primary steps and broad timeline for the first 6 months of development and implementation of a QMS to achieve certification of compliance to ISO 9001:2015

<i>QMS development and implementation activities</i>	<i>Month 1</i>	<i>Month 2</i>	<i>Month 3</i>	<i>Month 4</i>	<i>Month 5</i>	<i>Month 6</i>
Step 1 Gain formal commitment and endorsement of top leadership/management						
Step 2 Select a professional quality manager						
Step 3 Select a recognized training provider and/or where possible utilize the WMO QM mentor/twinning partnership initiative						
Step 4 Provide introductory QM training						
Step 5 Conduct a gap analysis						
Step 6 Conduct an initial QMRM. [This establishes the importance of the role of the QMRMs. It is appreciated that all aspects of the QMRM agenda will not be addressed at this early stage.]						
Step 7 Commence work on rectifying identified gaps						
Step 8 Identify processes and develop procedures						
Step 9 Establish levels of customer satisfaction and tools to acquire and measure this information						
Step 10 Identify and train appropriate staff to undertake the role of internal auditor						

Table 3. Primary steps and broad timeline for the second 6 months of development and implementation of a QMS to achieve certification of compliance to ISO 9001:2015

<i>QMS development and implementation activities</i>	<i>Month 7</i>	<i>Month 8</i>	<i>Month 9</i>	<i>Month 10</i>	<i>Month 11</i>	<i>Month 12</i>
Step 11 Conduct a first internal audit						
Step 12 Conduct a QMRM						
Step 13 Select a third-party organization to perform the ISO 9001:2015 certification of compliance						
Step 14 Conduct a second internal audit						
Step 15 Conduct a QMRM						
Step 16 Conduct a third internal audit if required						

Table 4. Primary steps and broad timeline for the third 6 months of development and implementation of a QMS to achieve certification of compliance to ISO 9001:2015

<i>QMS development and implementation activities</i>	<i>Month 13</i>	<i>Month 14</i>	<i>Month 15</i>	<i>Month 16</i>	<i>Month 17</i>	<i>Month 18</i>
Step 17 Conduct a QMRM						
Step 18 Prepare for the external audit						
Step 19 Conduct a third-party certification audit (stages 1 and 2)						
Step 20 Celebrate certification of compliance						

5.2 **Step 1 – Obtain formal endorsement of top management**

5.2.1 Clause 5.1 of ISO 9001:2015 emphasizes the need for demonstrated commitment from top management. In fact, it is a critical first step in the development and implementation of a QMS. The demonstration of commitment should involve formal endorsement, communicated to all staff.

5.2.2 Top management must ensure that the finances to support the QMS will be available. The proposed development and implementation of the QMS should be formally documented and include the proposed implementation strategy, a broad timeline and an estimated budget. It is strongly suggested that the early development and implementation stages of the QMS be within a project framework.

5.2.3 It is not possible within the context of this Guide to indicate the exact cost of implementing a QMS. The scope of the QMS and the costs of training, consultancies and certification bodies will differ significantly across the WMO community. However, this Guide points to some important questions concerning the financial commitment required. Although the answers to these questions will enable the development of a reasonably accurate budget, it would also be advisable to set up a contingency fund to cover indirect costs that may not have been identified initially. For example, it may be decided to upgrade QMS instrumentation to enhance the quality of the observation network.

5.2.4 A word of caution regarding this step: unless the formal endorsement and commitment of top management can be obtained, and the appropriate level of resources secured, attempting to implement a QMS could be a waste of time and resources. The failure of this process will have a significant and adverse impact on staff.

5.3 **Step 2 – Select a professional quality manager**

5.3.1 The appointment of a professional quality manager is a key factor to the success of a QMS. It is strongly recommended that a full-time staff member be appointed at a senior level, and it is beneficial for the implementation process if the officer has a knowledge of the business.

Note: It is appreciated that ISO 9001:2015 eliminated references to the requirement for a management representative. However, this does not remove the need for an overall management role for the QMS, in particular, during the development, implementation and ongoing sustainability of the QMS. Extensive practical experience has confirmed the importance and real need for a professional quality manager role.

5.3.2 The position will inevitably be the driving force behind the QMS and the primary focus for issues pertaining to the QMS. It requires an individual with a specific set of skills, knowledge and character traits that will earn him/her the trust of top management and direct access to it. See the guidelines for auditing management systems in ISO 19011:2011.

5.3.3 A generic job description and selection criteria for this key role is provided in Appendix 17, which may be used as a starting point for establishing such a role.

5.3.4 It is essential that the individual appointed has a strong desire for, and interest in, undertaking the challenges associated with developing and implementing a QMS. A forced or political appointment will potentially, if not inevitably, undermine the QMS and result in its failure.

5.4 **Step 3 – Select a recognized training provider**

5.4.1 It is strongly recommended that several potential training providers be interviewed, to ascertain their knowledge and relevant experience, and how well they would align with the culture of the organization. The interview process provides an opportunity to assess their

commitment to working with the organization. The level of interest they have shown prior to the interview in obtaining information about the activities of the organization and the products and services it provides should be ascertained.

5.4.2 The credentials of any potential training providers should be carefully assessed by checking their qualifications and course content. It is important that they are accredited trainers and can provide an introductory course that will “demystify” ISO 9001 for all staff involved in the QMS.

5.4.3 A basic set of questions for establishing the credentials and the suitability of potential QM consultants/training providers is provided in Appendix 18.

5.4.4 The WMO community has Member NMHSs with whom it may be useful to form a mentor/twinning partnership. The benefits include acquiring skills and knowledge from other Member NMHSs with mature QMSs as well as providing an opportunity to ask questions about QMSs. It is suggested that to identify a suitable mentor/twinning partner, the WMO Secretariat be approached in the first instance.

5.5 **Step 4 – Provide introductory quality management training**

5.5.1 An introductory training session for all staff involved in the QMS should be organized, starting with the core QM team including the Chief Executive Officer/Director. A basic introductory ISO training course helps to ensure the successful implementation of a QMS by providing sound understanding of the principles and practices pertaining to ISO 9001. Ideally, this course should be provided by a registered training organization with expertise in this area. Although not ideal, if a staff member has to conduct the training session, he/she must have a sound and demonstrated background in the subject matter combined with, wherever possible, formal training skills.

5.6 **Step 5 – Conduct a gap analysis**

5.6.1 A gap analysis is a technique for determining the steps to be taken to move from the current state to a desired future state. In the case of QMSs, a gap analysis is undertaken to clearly identify which clauses of ISO 9001 are currently not being fully addressed (or not addressed at all) and to develop remedial actions. The gap analysis should be conducted by members of the QM team/section who have formal auditing qualifications. Gap analyses can be conducted with small groups of staff. For example, a gap analysis can be conducted with the senior management group and a separate gap analysis with middle management and/or operational staff. It is not unusual to receive different responses to questions depending on the position and level of staff within the organization.

5.6.2 The two gap analysis tools (part A and part B) listed below provide a structured framework to assess the current status of a QMS in terms of fulfilling the ISO 9001 clauses:

- (a) Part A, Gap analysis, is aligned with the clauses of ISO 9001. The gap analysis template in Appendix 19 provides comments and notes to assist users.
- (b) Part B, Gap analysis findings, lists the findings and remedial actions that are required to close the identified gaps between ISO 9001 and the current management system of an organization (see Appendix 20).

5.6.3 An important consideration in using the gap analysis tools is that, for most staff, this will be an introduction to an audit-like process and the practical aspects of a QMS. It is therefore important that it is a positive experience from all perspectives. Any gap analysis or audit should be focused on the processes and the overall system, not the individuals following the practices and procedures provided.

5.7 Steps 6, 12, 15 and 17 – Conduct quality management review meetings at these steps

5.7.1 There are no specified time periods applicable to conducting quality management review meetings (QMRMs). However, they are essential during the initial development and implementation stages of the QMS and should be conducted on an as-required basis.

5.7.2 There is merit in conducting QMRMs following internal and external audits, to review the findings and plan for follow-up/corrective actions. Some organizations may also find it beneficial to conduct a QMRM prior to an external surveillance or certification audit, in order to identify gaps that can be filled prior to the external audit(s) being conducted.

5.7.3 Clause 9.3 of ISO 9001:2015 provides detailed specifications (inputs) for management reviews (QMRMs). Appendix 16 below provides a generic template that may be adapted for QMRM agenda and minutes.

5.7.4 As per previous comments in Chapter 4 of this Guide, under clause 5.1 of ISO 9001:2015, it is important that a member of top management chairs QMRMs. The meetings provide useful insight into the basic processes and enable management to respond accordingly. It is imperative that the management fully understand and appreciate the requirements under clause 9.3 and subclauses 9.3.2 and 9.3.3 of ISO 9001:2015. The secretarial duties should nominally be undertaken by the quality manager/section.

5.7.5 Attendees at QMRMs should include senior officers and other staff within the scope of the QMS, as appropriate, and the internal auditor(s) should also attend. As mentioned previously, a definition of top management” is provided in ISO 9000:2015.

5.8 Step 7 – Commence work on rectifying identified gaps

5.8.1 The outcomes of step 5 (gap analysis) and actions resulting from step 6 (QMRMs) will provide a priority for rectifying identified gaps.

5.8.2 It is important to monitor progress and to document the actions and results that will need to be considered at the next QMRM.

5.9 Step 8 – Identify processes and develop procedures

5.9.1 Developing and writing processes and procedures that are currently being followed is a critical component of a QMS. It is imperative that they are developed in close consultation with the staff who follow them as part of their duties. There may be merit in providing specific QMS staff with training in how to write procedures.

5.9.2 It is important to find a balance between overdocumenting and not providing sufficient information, while ensuring that processes and procedures are clearly articulated and unambiguous. Finding the right balance usually comes through experience, including learning from others who have been through the same or a similar process.

5.9.3 A process matrix (Appendix 3) is a key outcome of this step.

5.9.4 At the commencement of implementation, it is important to develop specific, measurable, attainable, relevant, timely and, where possible, automated key performance indicators (KPIs) that reflect the actual activities of the QMS.

5.10 **Step 9 – Measure customer satisfaction**

5.10.1 It is essential that appropriate client satisfaction measuring tools are established from the outset, so as to provide a baseline from which to assess improvement in service delivery. Standard ISO 9001 notes that there are several ways in which the level of client satisfaction can be measured.

5.10.2 Industry focus groups can be used as viable measuring tools where the organization communicates face to face with representatives of a particular industrial sector that it serves. Focus groups are also useful because they provide an opportunity to ask questions, clarify customer feedback and expectations, and develop strategies with the customer to rectify any problems. They can also help to establish a core reference group that will gain better knowledge and understanding of the environment in which the organization operates – this will add useful input for addressing clauses 4.1 and 4.2. It is important that the actions arising from these meetings and the levels of customer satisfaction thereby identified are fully documented and agreed by all the parties concerned. The (agreed) documented outcomes will enable the identification of trends in customer satisfaction over a specific period of time.

5.10.3 Customer survey tools can enable the QMS to reach a larger audience. However, it is notoriously difficult to get customers to respond to surveys. It takes a great deal of tenacity and patience to obtain a sufficient number of responses that will provide credible and meaningful feedback on customer satisfaction. When preparing a customer satisfaction survey, the following key points should be considered:

- (a) The reason for conducting the survey, its target group and the most appropriate time to conduct it should be clearly established;
- (b) The contents of the survey should be well organized;
- (c) A budget for the survey should be prepared;
- (d) The questionnaire should be well designed and the questions clearly formulated;
- (e) The method that will be used for the survey (email, web, hard copy, telephone, focus group, etc.) should be clearly defined;
- (f) The method for analysing the results should be clearly established;
- (g) The questionnaire should be pre-tested before finalization;
- (h) Dates for dispatching and returning the questionnaire should be set;
- (i) The survey should be conducted on a scheduled basis to provide continuity of feedback and trends in the data;
- (j) Those conducting the survey should display tenacity and patience when collecting the questionnaires;
- (k) The data analysis process should be clearly defined and implemented;
- (l) Due care should be taken in interpreting and evaluating findings;
- (m) Special attention should be paid to developing the actions needed to address the issues raised (root cause analysis);
- (n) A survey report should be disseminated to key stakeholders and, most importantly, the QMS staff.

5.10.4 A generic template for a customer satisfaction survey tool is provided in Appendix 7.

5.10.5 A customer feedback mechanism on the QMS web page can also be a useful tool.

5.11 **Step 10 – Identify and train staff to undertake the role of internal auditor**

5.11.1 It is critical that due care be taken in selecting staff to perform the role of internal auditor. Individuals who show potential as auditors should be given formal training by a registered training organization.

5.11.2 It is imperative that the required level of competence of all internal auditors is maintained via refresher training or, more importantly, active participation in the audit programme.

5.11.3 Apart from having the appropriate training, selected staff should also possess the necessary personal qualities and attributes that enable them to act in accordance with the principles of auditing. Standard ISO 19011:2011 lists six principles of auditing:

(a) **Integrity:** the foundation of professionalism

Auditors should perform their work with honesty, diligence and responsibility, observe the law and make the disclosures required by law and the profession.

(b) **Fair presentation:** the obligation to report truthfully and accurately

Audit findings, conclusions and reports should reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the individual being audited should be reported.

(c) **Due professional care:** the application of diligence and judgement in auditing

Auditors should exercise care in accordance with the importance of the task they perform and the trust placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.

(d) **Confidentiality:** integrity and security of information

Auditors should be prudent in the use and protection of the information acquired in the course of their duties. Auditors should not disclose information without appropriate authority unless there is a legal or professional obligation to do so.

(e) **Independence:** the basis for the impartiality of the audit and objectivity of the audit conclusions

Auditors should be independent of the activity being audited and should be free from bias and conflict of interest, wherever practical. Auditors should maintain an objective state of mind throughout the audit process to ensure that the audit findings and conclusions are based only on evidence.

(f) **Evidence-based approach:** the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process

Audit evidence should be verifiable. It will be based on samples of the information available, as an audit is conducted during a finite period of time and with finite resources. The appropriate use of samplings is closely related to the confidence that can be placed in the audit conclusions.

(Adapted from ISO (2011), pp. 4 and 5)

5.11.4 It is suggested that organizations obtain a copy of ISO 19011:2011, which provides excellent guidelines on auditing. A copy may be purchased from the ISO online store (<https://www.iso.org/store.html>).

5.12 Steps 11, 14 and 16 – Conduct internal audits

5.12.1 Conducting an audit and developing a robust internal audit schedule is a critical component of a QMS.

5.12.2 It is strongly recommended that an organization's internal auditors widely publish an audit schedule, as it will provide a useful planning tool for key stakeholders.

5.12.3 The internal audit process should cover all facets of preparing for and conducting audits based on a sound audit programme: audit scope, audit criteria, references, definitions, audit schedule, audit performance, follow-up audits, corrective action, audit documentation, audit failure and management review. A generic internal audit procedure is provided in Appendix 15.

5.12.4 Paragraph 5.11.3 above addressed the qualities required of auditors. However, it is also important to note that auditors must be objective and impartial and shall not audit their own work. This situation can be relatively easily achieved within a QMS internal audit environment. The quality manager should ensure that internal audits are conducted by staff who do not work in the area being audited. It should be noted that the exchange of internal auditors among different organizations can be a useful process. The exchange of auditors, where possible, can also be used to enhance the value of the audit and the individual auditor's competencies.

5.13 Step 13 – Select a certification body to conduct the certification audit

5.13.1 In the case of the certification body (third party or external auditor), the need for objectivity and impartiality is even more important. There are many organizations globally offering consulting services to assist in the development and implementation of a QMS.

5.13.2 It is important to note there are some organizations that, in addition to their consulting services, may also offer their services as the third-party certification body. This is totally inappropriate and removes the impartiality and objectivity from the process, and will create a potential conflict of interest. Any organization contemplating engaging a conformity assessment body should give it considerable thought, as the credibility of the QMS and its certification of compliance with ISO 9001 is underpinned by the independence of the third-party external audit process. See paragraph 5.11.3 of this Guide and ISO 19011:2011, in particular, subparagraph (e).

5.13.3 When selecting a certification organization, the QMS should consider the following:

- (a) Whether it complies with standard ISO/IEC 17021:2011, *Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems* (ISO/IEC, 2011), and whether it can demonstrate a positive track record;
- (b) Whether its profile and standard mark are credible from both national and international perspectives;
- (c) Whether it currently provides certification for organizations providing similar products and services;
- (d) Whether it can commit to providing strict and thorough audits and whether an auditor is available with a sound understanding and appreciation of the activities, products and services of the organization;

- (e) Whether it has a definitive fee structure for the three-year certification period including any costs associated with travel;
- (f) Whether it can obtain testimonials from current and former clients as to the quality of its services.

5.13.4 To ascertain further credentials pertaining to potential certification bodies, it is highly recommended to consult the website of the relevant national accreditation organization. This will provide a list of national certification bodies, and access can be obtained through the International Accreditation Forum website (<http://www.iaf.nu/>). Additional information on selecting a certification body may be accessed through the following ISO web page: <http://www.iso.org/iso/home/standards/certification.htm>.

5.14 **Steps 18 and 19 – Prepare for and perform an external audit**

5.14.1 Preparing for an ISO 9001 third-party certification audit can be a daunting experience for all concerned. However, the following are some guidelines for this process:

- (a) The organization should embrace the audit process as a positive experience, which will help to improve its processes, systems and overall quality of its products and services.
- (b) The organization should liaise with the certification body to establish dates for the audit that suit all concerned. Most importantly, the organization should not consider undergoing the certification audit unless there is a strong indication – based on the success of internal audits – that it will be successful. It may be useful to undergo a pre-audit provided by the certification body if funding allows.
- (c) All staff should be provided with adequate lead time to prepare for the audit. The proposed 5-month period for preparation for external audit (see Table 4) is a nominal period. The actual development and implementation of the QMS throughout the proposed 18-month minimum period should ensure a significant amount of the pre-external audit preparation has been done – if not, the implementation has not been undertaken correctly.
- (d) If there is a lack of confidence in the ability of the QMS to successfully undergo an external third-party audit, then it should be delayed until such time it is ready. To do otherwise would be setting up the QMS for failure, which is unacceptable.
- (e) The certification auditors should be briefed on any potential safety issues concerning the location they will visit.
- (f) All documentation that may be needed during the audit should be easily accessible (including reports of previous internal audits and QMRMs).
- (g) A culture should be developed within the QMS that encourages staff not to attempt to hide or cover up any known problem areas.
- (h) It should be noted that an audit finding of minor non-conformances is not a negative. In fact, it shows that the audit process is working by providing a mechanism for identifying potential risks to the QMS.

5.15 **Step 20 – Celebrate certification of compliance**

5.15.1 It is imperative that the achievement of certification of compliance to ISO 9001:2015 is appropriately recognized by top management and celebrated by all staff. In fact, it is a reward and recognition of the high standard of products and services they provide.

5.15.2 However, it must be remembered that certification of compliance is not the end of the QM journey, although it is a milestone. The findings of the external audit need to be reviewed at a QMRM, and the appropriate actions taken to address any remedial actions.

5.15.3 Importantly, the certification of compliance provides an excellent baseline on which to measure ongoing improvement of the organization.

KEY POINTS



1. Developing and implementing a QMS without the formal endorsement and commitment of top management should not be attempted.
 2. Conducting a gap analysis is a critical step as it identifies the current status of the existing management system relative to the standard – it provides a foundation for planning the development and implementation of the QMS.
 3. Ensuring that a significant body of evidence has been gathered, demonstrating the successful implementation of the QMS, prior to an external certification of compliance audit (for example, levels of customer satisfaction), is important.
 4. It is important that members of top management chair QMRMs.
 5. An organization that assists in the development and implementation of the QMS cannot also provide its services as the third-party certification body. This will create a potential conflict of interest.
 6. If there is a lack of confidence in the ability of the QMS to successfully undergo an external third-party audit, then the audit should be delayed until such time it is ready. To do otherwise would be setting up the QMS for failure, which is unacceptable.
-

APPENDIX 1. ENVIRONMENTAL SCANNING TOOL

<i>Environmental scanning tool (SWOT analysis)</i>	
Scan scope (quality management system)	
Date of scan	
Scan participants	

Notes

1. This template has been developed to assist in meeting the requirements of clause 4.1 of standard ISO 9001:2015, *Quality Management System – Requirements*.
2. The scan is underpinned by the traditional SWOT analysis methodology, which provides a proven and useful tool for identifying and analysing the strengths, weaknesses, opportunities and threats applicable to the environment in which the organization operates. Only those issues that are relevant to the organization's purpose and strategic direction and that affect, or have the potential to affect, its ability to achieve its intended outcomes should be considered.
3. The scan should be conducted at a minimum of once a year and ideally just prior to commencing the annual planning process.
4. A SWOT analysis is a process that can be used to identify an organization's strengths, weaknesses, opportunities and threats. This is discussed further below.
5. The external context considers issues from the following local, regional, national and international perspectives: legal, technological, competitive, market, cultural, social and economic.
6. The internal context considers the values, culture, knowledge and performance of the organization.

Step 1 – Strengths, weaknesses, opportunities and threats analysis

A SWOT analysis is a process that can be used to identify an organization's strengths, weaknesses, opportunities and threats.

Strengths are characteristics of the organization that allow operation more efficiently and effectively than competitors. Consider:

- What does the organization do well?
- What advantages does the business have over other internal sections or external organizations, including competitors?
- What makes the organization different from competitors?

Weaknesses are areas that are recognized as needing improvement. Consider:

- What can be done better?
- What causes problems or complaints (information from root cause analysis)?
- Which capabilities need modifying, strengthening or divesting for the future?

Opportunities are trends, circumstances or business opportunities that may be taken advantage of. Consider:

- What are the changes in technology or markets?
- What local and global events may be useful?
- What are the changes in customer/societal values?

Threats can be external or internal, and are anything that can adversely affect business or operations. External threats could be economic, new legislation or even a new competitor in the market. Internal threats could be a skill or staff shortage within the organization. Consider:

- What obstacles are there for ongoing operation?
- Are there any potential competitors to the business?

- Who might be the new competition?
- Are there any potential changes to staffing, products, services or technology that could threaten operation or business?

Step 2 – Categorize from the following national, international, regional and local perspectives

Legal:

- Possible changes in regulation/legislation
- Impacts of these changes on business
- Stability of government
- Outsourcing regulations
- Government bureaucracy – rules and regulations
- Legal constraints

Technological:

- Maturation of existing technologies
- Technological developments or trends that affect or could affect the business
- New product development and potential markets: government, international, resource sector, etc.
- Productivity improvements through automation
- Telecommunication infrastructure
- Online connectivity and digital data

Competitive:

- Competitors
- Differences from competitors
- Competitiveness of the organization and what affects its ability to compete
- Customer problems and complaints with current products and services

Market:

- General market conditions that affect the business
- Market direction
- Needs for the organization's products and services in the market
- Customer market technology opportunities

Cultural/social:

- Current or emerging trends in lifestyle
- Implications of these trends
- Demographic trends that may affect market size (growth rate, income, population shifts)
- Whether these trends represent an opportunity or a threat
- Changes in consumer behaviour
- Increasing environmental awareness
- Urbanization
- Consumer demands; personalization and high-end experiences
- Public demand for transparency and participation in decision-making

Economic:

- National and internal financial trends (trends in economic forces)
- Economic trends that may have an impact on business activity
- Emerging markets
- Economic factors: inflation, employment levels, supply, energy available or the global financial situation

Step 3 – Prioritize

Once the SWOT analysis is completed, use a prioritization process to identify the top four or five items in each section. Consider:

- What must be addressed immediately?
- What can be handled now?
- What needs researching further?

Develop and document:

- Realistic strategies to address each item
- Resources required – human and costs, if known

Steps 1 and 2 – Analyse and categorize

(use one line per item)

<i>International, national, regional and local</i>				
<i>Perspective</i>	<i>Strengths</i>	<i>Weaknesses</i>	<i>Opportunities</i>	<i>Threats</i>
Legal	1. 2. 3. 4. 5.			
Technological	1. 2. 3. 4. 5.			
Competitive	1. 2. 3. 4. 5.			
Market	1. 2. 3. 4. 5.			
Cultural/social	1. 2. 3. 4. 5.			
Economic	1. 2. 3. 4. 5.			

Step 3 – Prioritize

<i>Priority</i>	<i>Strengths</i>	<i>Weaknesses</i>	<i>Opportunities</i>	<i>Threats</i>	<i>Integrated in planning process (Y/N)</i>
	Priority 1:	Priority 1:	Priority 1:	Priority 1:	
	Strategy:	Strategy:	Strategy:	Strategy:	
	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	
	Priority 2:	Priority 2:	Priority 2:	Priority 2:	
	Strategy:	Strategy:	Strategy:	Strategy:	
	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	
	Priority 3:	Priority 3:	Priority 3:	Priority 3:	
	Strategy:	Strategy:	Strategy:	Strategy:	
	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	
	Priority 4:	Priority 4:	Priority 4:	Priority 4:	
	Strategy:	Strategy:	Strategy:	Strategy:	
	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	
	Priority 5:	Priority 5:	Priority 5:	Priority 5:	
	Strategy:	Strategy:	Strategy:	Strategy:	
	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	Resources/cost (if known or estimated only)	

APPENDIX 2. STAKEHOLDER ANALYSIS TEMPLATE

<i>Stakeholder/interested party name</i>	<i>Community sector/industry</i>	<i>Relationship/requirements/ interaction with the organization</i>	<i>Comments (if applicable)</i>

APPENDIX 3. PROCESS MATRIX

Objectives				Key performance indicators			
[Insert QMS objectives here]				[Insert KPIs associated with QMS objectives here]			
Core process	Purpose	Inputs	Outputs	Process owner	Process risks	Controls/resources	Monitors/measures
1. [Insert identified core process here]	[Provide a detailed description of the process purpose]	[Detail the inputs and dependencies for the process here]	[Detail the outputs (products and services) of the process here]	[Officer responsible for the process]	[Detail the identified risks associated with the process]	[Provide details of any controls applicable to the process and specific resources that are required for the process]	[Detail any monitors and measures applicable to the process]
2.							
3.							
4.							

APPENDIX 4. QUALITY POLICIES

“QMS name” [insert name here]

Quality policy [sample only]

The “QMS name” is committed to ensuring the provision of high-quality products and services to enhance the safety and economy of operations within the region of responsibility.

“Organization name” is focused on improving the quality, consistency and utility of the service in line with the identified needs of key stakeholders by fostering innovation and continual improvement through the ongoing review of quantitative and qualitative measures of performance.

This policy will be underpinned and sustained by practical application of the seven principles of quality management and compliance with national and international regulatory requirements.

“QMS”/Organization Director

Date __ / __ / __

WMO QUALITY POLICY

WMO programmes and Members are to adopt a quality management approach based on the International Organization for Standardization (ISO) standard ISO 9001:2015, *Quality Management Systems – Requirements*, to assist in:

- Understanding the purpose and context in the community in which the organization operates
- Planning the strategic direction of the organization
- Identifying and providing appropriate resources to achieve the planned objectives
- Achieving the consistent delivery of high-quality products and services
- Evaluating and reviewing organizational practices, procedures and processes to drive continual improvement

This policy will be underpinned and sustained by practical application of the seven principles of quality management and compliance with national and international regulatory requirements.

The following seven principles have been identified as providing a sound foundation for achieving the organization’s goals and objectives:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Improvement
- Evidence-based decision-making
- Relationship management

WMO

Date __ / __ / __

APPENDIX 5. AUDIT QUESTIONS FOR TOP MANAGEMENT

	Reference clause in ISO 9001:2015
Leadership and commitment	
<i>A. Context of the organization</i>	
What are the internal and external issues that affect your organization?	4.1
Has the quality management system (QMS) identified and addressed these issues as part of the planning process?	4.1
What changes (if any) are currently affecting the QMS?	4.1
Have the statutory and regulatory requirements that affect the QMS been defined?	4.2
<i>B. Leadership and commitment for the QMS</i>	5.1.1
How do you demonstrate accountability for the effectiveness of the QMS?	5.1.1.a
How do you ensure that the QMS quality policy and quality objectives are established and aligned with the strategic direction of the organization?	5.1.1.b
What role do you play in ensuring that the QMS has the necessary resources for operation?	5.1.1.e
What role do you play in communicating the importance of conforming to the requirements of the QMS?	5.1.1.f
What role do you play in ensuring that the QMS meets its objectives?	5.1.1.g
What role do you play in directing and supporting staff to contribute positively to the QMS?	5.1.1.h
How do you promote continual improvement within the QMS?	5.1.1.i
What role do you play in supporting other managers within the QMS to demonstrate leadership in their area of responsibility?	5.1.1.j
<i>C. Process approach</i>	
What is your understanding of the process approach and how is it promoted within the organization?	5.1.1.d
How is the QMS integrated within the organization's business processes?	5.1.1.d
Has the organization established and implemented the processes needed for the QMS?	5.1.1.d
Has the organization determined the inputs and outputs expected from these processes?	4.4.1.a
Has the organization determined the sequence and interaction of these processes?	4.4.1.b
Has the organization assigned the responsibilities and authorities for these processes?	4.4.1.e
How does the QMS evaluate these processes and implement any changes that are needed to ensure the processes achieve their intended results?	4.4.1.g
<i>D. Risk-based thinking</i>	
What role do you play to ensure any risks and opportunities identified as possibly affecting the organization's ability to achieve products or services conform and meet customer requirements?	5.1.1.b
How are risks within the QMS identified and managed? How are they escalated?	6.1.1
How are potential risks that affect the QMS addressed and monitored?	6.1.1
<i>E. Customer focus</i>	5.1.2
What role do you play in ensuring that customer requirements are determined, understood and met?	5.1.2.a
What mechanisms are in place to ensure that applicable statutory and regulatory requirements are determined, understood and met?	5.1.2.a
How do you ensure that the focus on the consistent provision of products and services is maintained throughout the organization?	5.1.2.a
How do you ensure that the QMS maintains its focus on enhancing customer satisfaction?	5.1.2.c
<i>F. Quality policy</i>	5.2

	<i>Reference clause in ISO 9001:2015</i>
What role do you have in establishing the QMS quality policy? How does the quality policy reflect the purpose and context of your organization and how was this determined? Was the quality policy utilized when formulating the QMS quality objectives? How does the quality policy account for the organization's commitment to satisfy requirements? Does the quality policy commit to the organization's continual improvement? How is the quality policy communicated throughout the organization? Is it available as documented information?	5.2.1 5.2.1.a 5.2.1.b 5.2.1.c 5.2.1.d 5.2.2.a/5.2.2.b
<i>G. Organizational roles, responsibilities and authorities</i>	5.3
Are roles, responsibilities and authorities defined within the QMS? Is each role clearly assigned, communicated and understood within the organization? Does each employee have an up-to-date job description and duty statement? Are duty statements reviewed on a scheduled basis to ensure they are current? Which role is responsible for reporting on the performance of the QMS to top management?	5.3 5.3 5.3 5.3 5.3
<i>H. Management review</i>	
What role do you have in quality management reviews? How often are these reviews carried out? Who is involved in the management reviews? How is the information presented? What outputs are derived from these management reviews? What documented information is retained as evidence of the results of management reviews and where is this information available?	9.3 9.3.2 9.3.2 9.3.2 9.3.3 9.3.3

APPENDIX 6. CUSTOMER RECORDS TEMPLATE

Customer name and location of operations	Products/services received			Review of customer requirements		Method of review	Service level agreement or contract details (number, validity, place of storage, etc.)	Comments including perceived and known level of customer satisfaction and the potential impact of products/services on customer operations
	Specific requirements	Controls	Post- delivery activities	Review period: 12/18/24 months or other	Last review date			

APPENDIX 7. CUSTOMER SATISFACTION SURVEY

"QMS" customer satisfaction survey		
Please answer the following questions by ticking the appropriate box(es)		
CLIENT INFORMATION		
1. Please indicate your industry sector:		
<input type="checkbox"/> Aviation	<input type="checkbox"/> Mining/oil and gas industry	
<input type="checkbox"/> General public	<input type="checkbox"/> Agriculture	
<input type="checkbox"/> Marine	<input type="checkbox"/> Other (please specify)	
Other <input type="text"/>		
Please specify your role: <input type="text"/>		
PRODUCTS AND SERVICES		
2. Which <u>products</u> and <u>services</u> provided by "QMS" do you use?		
<input type="checkbox"/> Tropical cyclone warning	<input type="checkbox"/> Public weather forecast	
<input type="checkbox"/> Severe thunderstorm warning	<input type="checkbox"/> Coastal waters	
<input type="checkbox"/> Fire Weather	<input type="checkbox"/> Terminal aerodrome forecast	
<input type="checkbox"/> Other (please specify):		
Other <input type="text"/>		
The following are general questions about "QMS" products and services:		
3. How would you rate the <u>professionalism</u> of "QMS" personnel?		
<input type="radio"/> Highly professional	<input type="radio"/> Professional	<input type="radio"/> Unprofessional

4. How would you rate the <u>responsiveness</u> of "QMS" personnel?		
<input type="radio"/> Always responsive	<input type="radio"/> Mostly responsive	<input type="radio"/> Unresponsive
5. How would you rate the overall <u>accuracy</u> of "QMS" products and services?		
<input type="radio"/> Always accurate	<input type="radio"/> Usually accurate	<input type="radio"/> Inaccurate
6. How would you rate the overall <u>timeliness</u> of "QMS" products and services?		
<input type="radio"/> Always on time	<input type="radio"/> Mostly on time	<input type="radio"/> Never on time
7. How would you rate the <u>ease of use</u> of "QMS" products and services?		
<input type="radio"/> Very easy to use	<input type="radio"/> Mostly easy to use	<input type="radio"/> Not easy to use
8. How would you rate the <u>accessibility</u> of "QMS" products and services?		
<input type="radio"/> Easy to access	<input type="radio"/> Mostly easy to access	<input type="radio"/> Not easy to access
9. Does "QMS" contribute to enhancing the <u>economic viability</u> of operations?		
<input type="radio"/> Always	<input type="radio"/> Mostly	<input type="radio"/> Rarely
10. Does "QMS" contribute to enhancing the <u>safety</u> of operations?		
<input type="radio"/> Always	<input type="radio"/> Mostly	<input type="radio"/> Rarely
11. Does "QMS" <u>meet the needs</u> of the organization?		
<input type="radio"/> Always	<input type="radio"/> Mostly	<input type="radio"/> Rarely
12. What overall <u>impact</u> do you believe "QMS" is having on operations?		
<input type="radio"/> Always positive	<input type="radio"/> Mostly positive	<input type="radio"/> Negligible
13. What is your level of <u>overall satisfaction</u> with "QMS"?		
<input type="radio"/> Very satisfied	<input type="radio"/> Fairly satisfied	<input type="radio"/> Dissatisfied
The following are specific questions about "QMS" products.		

The following are specific questions about "QMS" products:	
14. What communication interfaces do you use to access "QMS" products and services?	
<input type="checkbox"/> Internet	<input type="checkbox"/> AFTN
<input type="checkbox"/> Other (please specify):	<input type="checkbox"/> GTS
<input type="checkbox"/> NAIPS	
Other <input type="text"/>	
15. What communication systems do you have installed or will be installing to receive <u>graphical products</u> ?	
<input type="text"/>	
16. What information or features would you like presented as a graphical map display?	
<input type="checkbox"/> Colour codes displayed on map	
<input type="checkbox"/> Text can be accessed (for example, via mouse click)	
<input type="checkbox"/> Graphics can be displayed	
<input type="checkbox"/> Other (please specify):	
Other <input type="text"/>	
17. Are there any products, information sources or content that you would like included on the "QMS" website?	
18. Can you suggest ways that could <u>improve</u> any of the products and services provided by "QMS"?	
<input type="text"/>	
Completion of the following is optional:	
Name	<input type="text"/>
Address	<input type="text"/>
Area/post code	<input type="text"/>

APPENDIX 8. QUALITY MANAGEMENT SYSTEM DUTY STATEMENT

“QMS” duty statements – duties pertaining to ISO 9001

The following are suggested duties that could be included in staff duty statements at the appropriate level. The suggested top management statement demonstrates its strong commitment to the quality management system (QMS).

Level: Top management – Chief Executive Officers, Directors, Deputy Directors
Lead activities to ensure the quality and effectiveness of the QMS and [as appropriate] the ongoing development, implementation and maintenance of the QMS to achieve and maintain certification of compliance with ISO 9001:2015
Level: Section heads
Plan and develop strategies for the quality and effectiveness of the QMS products and services and [as appropriate] the ongoing development, implementation and maintenance of the QMS to achieve and maintain certification of compliance with ISO 9001:2015
Level: Operational managers
Manage the implementation of strategies for the quality and effectiveness of the QMS products and services and [as appropriate] the ongoing development, implementation and maintenance of the QMS to achieve and maintain certification of compliance with ISO 9001:2015
Level: All other levels
Participate in ensuring the quality and effectiveness of the QMS products and services and [as appropriate] the ongoing development, implementation and maintenance of the QMS to achieve and maintain certification of compliance with ISO 9001:2015

APPENDIX 9. RISK REGISTER TEMPLATE

Risk level matrix

[illegible]

Key

The relationship between consequence and likelihood determines the level of risk according to the key below, for example, a "medium" consequence with "moderate" likelihood equates to a risk rating of "significant".

Likelihood	Consequence				
	Negligible	Low	Medium	High	Extreme
Almost certain	Significant	Major	High	Severe	Severe
Likely	Moderate	Significant	Major	High	Severe
Moderate	Low	Moderate	Significant	Major	High
Unlikely	Negligible	Low	Moderate	Significant	Major
Rare	Negligible	Negligible	Low	Moderate	Significant

Consequence and likelihood tables – to be used in conjunction with the risk level matrix

(Adapted from ISO 31000:2009 (ISO, 2009b))

<i>Type of impact</i>	<i>Consequence</i>				
	<i>Negligible</i>	<i>Low</i>	<i>Medium</i>	<i>High</i>	<i>Extreme</i>
Operations/information technology (activities and/or service delivery)	Insignificant disruption to core services Negligible impact on service provision	Minor disruption to core services Customers inconvenienced	Significant disruption to core services (less than 24 hours) Customers significantly inconvenienced	Severe disruption to core services Continuing difficulties in servicing customers over a prolonged period (1–2 days)	Long-term disruption or permanent loss of capability to provide core services or provide services to customers for 2 days or more
Finance, fraud and protective security	Minor financial loss that can be absorbed by the section and/or programme Minor damage to assets	Financial loss (up to 10% of funding requiring reprioritization and/or reallocation of available funds) Petty theft/minor fraud Limited damage to national security and/or harm to entity assets	Major financial loss of 10–20% of funding requiring the curbing of non-critical programmes Significant overexpenditure High impact – internal or external fraud Major harm to organization assets	Financial loss of 20–40% of funding requiring temporary suspension of programmes Major and systemic external or internal fraud resulting in significant loss of assets or funds Damage to national security and major harm to national security assets	Inability to fund core programmes due to a financial loss of over 40% of funding Serious damage to national security, government entity operations, commercial entities or members of the public
Data and information (including privacy)	Insignificant impact on internal and external users, stakeholders and clients Negligible impact on privacy of an individual and easily rectifiable	Minimal impact on internal and external users, stakeholders and clients Minor impact on privacy of an individual, which can be addressed by taking additional measures	Significant impact on internal and external users, stakeholders and clients Significant impact on privacy of an individual or a low level of impact on privacy of a number of individuals	Severe impact on internal and external users, stakeholders and clients Very significant impact on privacy of an individual or a significant impact on privacy of a number of individuals	Long-term impact on internal and external users, stakeholders and clients Extremely serious impact on privacy of an individual, or severe impact on a number of individuals
Safety and environment	Nil or negligible injuries that may require only local first aid Insignificant impact on the environment	Minor injury (reversible health damage) that may require medical attention and limited ongoing treatment Minimal impact on the environment	Serious injury requiring medical treatment and ongoing treatment or lost time Significant impact on the environment	Extensive injuries that are irreversible or require extensive surgery/medical treatment Severe impact on the environment	Fatality or fatalities attributed to organization actions or omission Long-term or permanent damage to the environmental viability of the impact area

<i>Consequence</i>					
<i>Type of impact</i>	<i>Negligible</i>	<i>Low</i>	<i>Medium</i>	<i>High</i>	<i>Extreme</i>
Public image, internal and external stakeholder concerns and reputation	Minimal (or nil) effect on reputation Resolved through day-to-day management	Minor isolated concerns from the public, customers or management team Organization not seen as an employer of choice	Significant and sustained public client/stakeholder concern Adverse media publicity through real or perceived service failure	Major loss of confidence by key stakeholders including political intervention Organization subject to formal inquiry	Abolition of the organization or significant reduction in authority Inability to deliver on mission and objectives or government agreed outcome

Likelihood/probability (of consequences/impact)

<i>Rare</i>	<i>Unlikely</i>	<i>Moderate</i>	<i>Likely</i>	<i>Almost certain</i>
Could happen but probably never will	May occur only in exceptional circumstances	Might occur at some time	Will probably occur in most circumstances	Expected to occur

Source: Australian Government, Bureau of Meteorology (2015)

APPENDIX 10. COMPETENCE NEEDS ANALYSIS

Competence needs analysis

Conducted by:

Date: __ / __ / __

Employee name:				Position title/number:					
Duties (see duty statement)	Competence required	Competence		Type of training required	Title of competence framework if one already exists	Proposed training provider	Where are records retained?	Validity period	Date achieved
		Yes	No						

APPENDIX 11. COMMUNICATIONS PLAN

<i>Communications method</i>	<i>Target audience</i>	<i>Date</i>	<i>Responsibility</i>
[How will you get your messages out?]	[Who are you trying to reach with this method?]	[When should it happen?]	[Whose job is it?]
External			
Internal			

APPENDIX 12. PROJECT TEMPLATES

Title project Overview

1. Project definition				
Project title				
Programme				
Start date / end date				
Stakeholders	[List the key stakeholders or stakeholder groups who will be affected by the initiative. Stakeholders provide or receive a service to or from the project. They are critical to the success of the project.]			
Related projects	[List any related projects that are dependent on this initiative, or projects that are interdependent on this initiative or projects upon which this initiative is dependent. These may share data, function, technology or staff with the project.]			
Project authority	[Detail the lines of authority and responsibility]			
Project funding	[Identify the source(s) of funding]			
<i>Project team</i>	<i>Name</i>	<i>Position/section</i>	<i>Phone</i>	<i>Email</i>
Project sponsor				
Project manager				
2. Project description				
National objective	[Include overall QMS objective]			
Project objectives	[List the objectives of the project. Objectives need to be specific (addressing client requirements) and measurable]			
Background	[Introduction or background to the project including, where appropriate, identified client requirements]			
Project description	[Provide a concise description of the project]			
Scope	[Identify the broad boundaries of the project and what the project is designed to achieve, with a specific focus on any customer requirements. It is also useful to consider what may be outside the scope of the project.]			
Deliverables	[What are the project deliverables?]			
3. Justification				
Expertise	[Provide a description of the expertise necessary to undertake the project]			
Benefits	[Provide an explanation as to why this initiative has been identified as a priority and associated desired benefits/outcomes. Include links to QMS objectives, priorities, strategic plans and meeting identified client needs.]			
Impact	[What are the consequences if the project is not undertaken?]			
4. Communication strategies				
<i>Description</i>	<i>Target audience</i>	<i>Delivery method</i>	<i>Frequency</i>	<i>Responsibility</i>

[Notes: How are details of the project going to be communicated to the stakeholders, in particular key customers? Include meetings, liaison and progress reports. Progress reports should occur at agreed predetermined time intervals or at key milestones. They should include the actual progress against the planned schedule (including cost, time and performance).]

5. Evaluation methods			
<i>Description</i>	<i>Methodology</i>	<i>Target</i>	<i>Responsibility</i>

[Note: Clearly define the KPIs that will indicate that the initiative has been successfully completed.]

6. Milestones				
Milestone	Accountability	Dates	Status	
1				
2				
3				
4				
5				
6				
7. Risk summary				
Risk description	Likelihood	Impact	Risk	
8. Budget				
Description	2017–2018	2018–2019	2019–2020	Ongoing
Overheads				
Total				

Title project
Statement of requirements

Version control

<i>Version</i>	<i>Author</i>	<i>Date</i>	<i>Comments</i>

Version acceptance

<i>Approver</i>	<i>Signature</i>	<i>Date</i>	<i>Comments</i>

Note: Approval of this statement of requirements indicates an understanding and formal agreement that the product and/or service should be developed and implemented in accordance with these requirements.

Title project
Statement of requirements

Purpose

[1. State the purpose of the project. This is a brief statement of what the project is and what it covers. Flow diagrams can be useful to illustrate the system (or part thereof) that the project covers.

Note that the purpose of the statement of requirements is to specify the services and user requirements that need to be satisfied and achieved for the project to meet its objectives. References supporting the requirements should be provided.

As required, this document will be used as a reference for technical specifications, training documentation, and the development of user and acceptance testing criteria. Therefore, it can be useful to assign reference numbers and priorities to each requirement for tracking and subsequent evaluation.]

Background

[2. Who has requested this project? What are the driving issues related to this project? Have there been changes to legislation, technology, observational programmes, staff reconfiguration, etc.?)

Products and services

[3. Indicate what products and services are required (if any). This may be an existing or new product or service. Provide an example if available.]

Specific staff (optional)

[4. If the project or its outputs require interaction or involvement of specific staff, then list all inputs and actions necessary to perform required duties. These include data inputs and outputs, accessibility and usability requirements as well as training and ongoing assessments.]

Service requirements

[5. Define the service requirements applicable to this project. These may include information technology, communication, display systems, interface, input data capability, data format, data archiving, documentation, training and dissemination methods. Include references and supporting documentation that provide the bases for the service requirements. Include key material and weblinks in the appendices and references.]

Service level requirements

[6. Operational hours, support requirements and return to service expectation. Include responsibilities and whether approval has been obtained by the section responsible. Also include training requirements for system maintenance and support.]

Quality management requirements

[7. Include additional requirements for ensuring QM procedures are followed. For example, certification of instrumentation or changes to competency training.]

Author: _____

Date: ____/____/____

Title project – status report

1. Project overview					
Project title					
Quality management system					
Start date / end date					
<i>Project team</i>	<i>Name</i>	<i>Position/section</i>	<i>Phone</i>	<i>Email</i>	
Project sponsor					
Project manager					
2. Project summary					
Project objectives		[List the objectives of the project. Objectives need to be specific (addressing customer requirements) and measurable]			
Project scope		[Identify the broad boundaries of the project and what the project is designed to achieve with a specific focus on any customer requirements. It is also useful to consider what may be outside the scope of the project.]			
Project deliverables		[List the project deliverables]			
Progress summary		[Summarize the progress of the project so far. The actual progress against the planned schedule (including cost, time and performance) should be included.]			
3. Status report against milestones					
<i>Milestone</i>	<i>Baseline date</i>	<i>Revised target date</i>	<i>Status</i>	<i>Achievements</i>	<i>Issues and outlook</i>
1.					
2.					
3.					
4.					
5.					
6.					
4. Status report against functional target					
<i>Functional target</i>		<i>Status</i>	<i>Achievements</i>		<i>Risk</i>

Note: This table is used as input to management review meetings.

Key:



On schedule and on budget



Minor delays or budgetary issues



Serious delays or budget overspend

Title project – acceptance

1. Project overview				
Project title				
Quality management system				
Start date / end date				
<i>Project team</i>	<i>Name</i>	<i>Position/section</i>	<i>Phone</i>	<i>Email</i>
Project sponsor				
Project manager				
2. Project description				
Project objectives	[Include project identifier as per section's operational plan. List the objectives of the project. Objectives need to be specific (addressing customer requirements) and measurable.]			
Project description	[Provide a concise description of the project]			
Scope	[Identify the broad boundaries of the project and what the project is designed to achieve with a specific focus on any client requirements. It is also useful to consider what may be outside the scope of the project.]			
Deliverables	[List the project deliverables]			
3. Acceptance information				
Method	[Describe the mechanism used to obtain formal agreement for deployment]			
Representatives	[Identify who was involved in acceptance, including which functional areas; include name, project role or title, section, organization]			
Documentation	[Describe documents used as supporting material during acceptance, including whether the documents required a formal signature for approval]			
4. Acceptance checklist				
<i>Item</i>	<i>Question</i>			<i>Functional area</i>
4.1	Did you formally approve plan(s) that identify operational requirements, service readiness, training, knowledge transfer, roll-out strategy, and other core activities/factors that are necessary to effectively move a technology-based product and/or service to an operational status? For example, did you approve a deployment plan, training plan, operations and maintenance plan, and/or product release plan?			Yes No
4.2	Did you formally accept all test results?			Yes No
4.3	Do you accept the product and/or service as ready to be operational?			Yes No
4.4	Do you agree the product and/or service has sufficiently met the stated business goals and objectives?			Yes No
4.5	Do you fully understand and agree to accept all operational requirements, operational risks, maintenance costs, and other limitations and/or constraints imposed as a result of making the product and/or service operational?			Yes No

Note: Please respond to each question. For each "no" response, include an issue in the open issues section below.

5. Open issues	
<i>Issue</i>	<i>Planned resolution</i>

Note: Describe any open issues and plans for resolution within the context of formally accepting deployment of the product and/or service. Include an open issue for any "no" responses in the acceptance checklist section above.

6. Project acceptance			
<i>Approver</i>	<i>Signature</i>	<i>Date</i>	<i>Comments</i>

Note: Approval of this project acceptance indicates an understanding and formal agreement that the product and/or service has been developed and implemented in accordance with the project plan and is now complete or operationally implemented.

APPENDIX 13. EXTERNAL PROVIDERS REGISTER

External providers register

[illegible]

External provider information									
	<i>The organization shall communicate the following requirements to the external provider for :</i>								
QMS (programme/section) receiving external products and services	Product or service or process required	the approval of:			Competence		Communications	Performance	Verification/validation
		Products and services	Methods, processes and equipment	Release of products and services	Include required qualifications of persons	If required, state qualification	With the QMS	Control and monitoring applied by the QMS	Activities that the QMS will undertake at premises

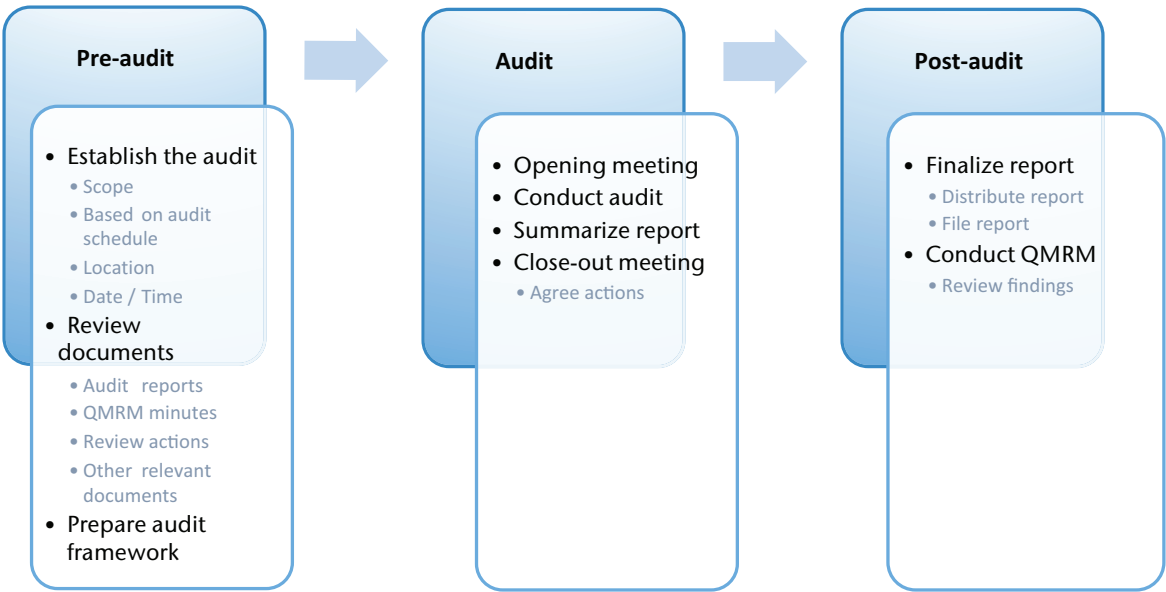
APPENDIX 14. NON-CONFORMANCE PROCEDURE

Sample procedure for rectifying and reporting non-conforming forecast products and corrective actions

1. Awareness of non-conforming products in the delivery of aviation meteorological services is normally identified through:
 - (a) Recognition by the duty aviation meteorologist that a product is outside the set criteria articulated in ICAO Annex 3 (Meteorological Service for International Air Navigation) for terminal aerodrome forecasts.
 - (b) Real-time aviation industry feedback while the product is current.
 - (c) Feedback from the aviation industry after the operational currency of the product, for example, at a consultative meeting or via web feedback (complaint).
 - (d) A request as a result of an aeronautical meteorological incident.
 - (e) A request as a result of an aviation safety investigation.
2. Non-conformities, as identified in the following circumstances, will be eliminated or rectified as expediently as possible when:
 - (a) There is an operational version of the product currently available to the aviation industry and the non-conformance is brought to the attention of the duty aviation meteorologist who will expediently issue an amendment to rectify the non-conformance.
 - (b) There is an operational version of the product currently available to the aviation industry and the non-conformance is identified by the duty aviation meteorologist who will expediently issue an amendment to rectify the non-conformance, for example, an amendment is required as per articulated criteria.
 - (c) The non-conformance has been identified after the operational currency as the result of a request from an investigative body.
 - (d) A non-conformance is raised at an aviation industry forum. Every endeavour shall be made to identify the product(s) in question and the officer responsible for issuing the product(s). Rectification will then be undertaken as expediently as possible.
 - (e) A non-conformance is identified after the operational currency through other (internal) means such as post-analysis or other investigation. The non-conformance should be brought to the attention of forecasters, and any corrective action expediently taken.
3. Outcomes pertaining to a non-conformance, which should be reported back to the individual or organization that notified the non-conformance.
4. A monitoring log of investigations maintained on the internal shared drive.
5. Logging of all action items from an identified non-conformance (incident). The preventive action(s) (based ideally on a root-cause analysis), recommended are then addressed from several perspectives:
 - (a) By identifying and assessing the competencies appropriate to the delivery of aviation weather services and providing the appropriate training as applicable;

- (b) In the event of an incident, by identifying preventive actions under the four subheadings of: procedural, information/data, infrastructure, and training or other;
 - (c) In the event of an incident, by identifying preventive actions and responding to recommendations that arise out of the formal aviation safety investigation report;
 - (d) The corrective actions from any investigation are standing agenda items at the quality management review meetings.
-

APPENDIX 15. INTERNAL AUDIT PROCESS



APPENDIX 16. QUALITY MANAGEMENT REVIEW MEETING TEMPLATE

“QMS”

Quality management review meeting

AGENDA

Date: __ / __ / __

Time:

Venue:

Attendees:

Chairperson:

<i>Meeting objective</i>	<i>Notes: Root causes, decisions, actions</i>	<i>Officer responsible</i>	<i>Target date</i>
1. Review the “QMS” outstanding actions			
2. Report on any changes in external/internal issues relevant to “QMS”			
3. Report on internal/external audit findings			
4. Update on customer satisfaction and feedback including trends			
5. Update on the progress of “QMS” objectives			
6. Report on process performance, non-conformities/corrective actions and monitoring/ measuring activities			
7. Review performance of external providers and external providers register			
8. Report on adequacy of resources			
9. Update on “QMS” risks and opportunities for improvement			

APPENDIX 17. QUALITY MANAGER ROLE

QUALITY MANAGER

Job description

Role of the quality management section

The fundamental role of the quality management (QM) section is to deliver a comprehensive range of QM services, skills and knowledge. These are to be provided on a cross-cutting and cross-programme basis to enable the organization to integrate a quality management system (QMS) into all facets of product and service delivery and achieve certification of compliance with ISO 9001:2015, *Quality Management Systems – Requirements*.

Function

The occupant's prime responsibility under the broad policy control and direction from the head of the organization, and in conjunction with top management, is to provide specialist knowledge to the organization on a range of comprehensive QM services, skills, knowledge and advice.

The position requires sound knowledge of ISO 9001:2015, *Quality Management Systems – Requirements*, and competence as a lead auditor of management systems in accordance with ISO 19011:2011, *Guidelines for Auditing Management Systems*.

The position requires a high level of expertise and management skills, as the occupant will be required to manage the broad range of activities provided by the QM section. These will include analysis and assessment of service and product delivery procedures, planning, training, QMS implementation and internal audits. It will also require strong leadership in assisting and mentoring staff, including top management, through the ongoing audit process and continual improvement of procedures pre- and post-certification.

The position requires high levels of strategic and change management skills. The occupant is required to build cross-programme partnerships and communicate effectively with organizational staff at all levels. He/she is required to possess a high standard of written and oral communication skills, to be able to effectively manage change and to follow projects through to completion. The occupant is also required to show independent judgement.

Competencies/qualifications

Professional

A degree or diploma from an internationally recognized educational institution or other comparable qualification that is appropriate to the duties.

Quality management and auditing

Tertiary studies in the area of QM as part of a degree or diploma from an internationally recognized educational institution. The occupant must be qualified to perform internal audits, and possess a qualification as a lead auditor of management systems (ISO 9001) in accordance with ISO 19011.

Duty statement

Under general direction from the head of the organization, the quality manager will:

1. Manage and lead the QM section, providing support to top management;
2. Ensure realization of the organization's priorities, including through the coordination of work across the organization;

3. Provide strategic input and advise to top management on strategic, operational and tactical issues, risks and solutions;
4. Design and undertake appropriate evaluation and performance reporting for the organization;
5. Formulate, plan and promote the medium- and long-term strategic direction of quality objectives, policies and systems for the organization;
6. Provide expert advice and guidance on QM principles and systems to top management, and engage and collaborate with internal stakeholders to achieve QMS outcomes and facilitate cooperation;
7. Lead the planning, design, development and documentation of QMSs for designated sites, functions, products, services and processes that achieve and maintain ISO 9001:2015 certification;
8. Build a network of QM practices across the organization by providing professional development, training and mentoring through the ongoing audit process and continuous improvement of procedures pre- and post-certification.

Selection criteria

Applicants are required to possess the following selection criteria:

1. **Coordination.** Demonstrated coordination skills. The ability to coordinate activities throughout their entire life cycle, including feasibility, planning, implementation, evaluation and review. The ability to think and plan strategically in terms of coordinating the management of change and achievement of intended results.
 2. **Quality management and auditing.** Sound knowledge of QMS practices and principles, and sound appreciation of the requirements for third-party certification against the ISO 9001:2015 QM standard. Demonstrated ability to conduct internal audits against ISO 9001:2015 and the demonstrated ability to attain qualifications as a lead auditor of management systems in accordance with ISO 19011:2011.
 3. **Corporate governance.** Demonstrated sound knowledge and experience in the application of corporate governance principles and practices combined with effective decision-making skills.
 4. **Delivery of products and services.** Demonstrated knowledge of the roles and interactions of the various QMS sections combined with demonstrated knowledge of the delivery of products and services at international, national and regional levels.
 5. **Customer focus.** Commitment to high-quality customer services and ongoing improvement through a focused approach to the QM principles and practices while meeting identified customer needs.
 6. **Communication skills.** Demonstrated ability to communicate clearly across all levels of the organization through oral and written means. Ability to negotiate persuasively and to listen, understand and adapt to different audiences, particularly top management and broad sectors of the community.
 7. **Drive and commitment.** Demonstrated proactive, decision-making skills and motivation to commit to action. Self-awareness, personal courage, resilience and commitment to personal development.
-




APPENDIX 18. QUESTIONS FOR POTENTIAL QUALITY MANAGEMENT CONSULTANTS/TRAINING PROVIDERS

1. Can you provide an overview of your quality management (QM) background? Are you certified as being compliant against the ISO 9001 QM standard?
 2. Do you see the quality management system (QMS) presenting any unique challenges that you have or have not faced previously? If so, what are those challenges and how did you deal with them?
 3. Do you believe the drivers to adopt the ISO 9001 QM standard are legitimate?
 4. What approach do you believe would be the most appropriate for the organization to achieve certification in accordance with ISO 9001?
 5. What would you need from the organization to initiate the project?
 6. What strategies do you employ to maintain a close working relationship with the organization and to ensure success while minimizing time and costs?
 7. Can you provide examples of work you have previously done for other organizations?
 8. If you are selected for or accept the challenge of assisting the organization and it does not achieve certification the first time, what action would you take to ensure that certification is achieved?
 9. Do you provide QM training services and, if so, do you have qualified trainers? Are you registered as an internationally recognized training organization?
 10. Do you guarantee your services?
 11. Can you provide a fixed schedule of charges/fees?
-

APPENDIX 19. GAP ANALYSIS (PART A)




<i>Gap analysis tool</i>	
Quality management system (QMS)	
Scope of gap analysis	
Gap analysis date	
Gap analysis completion date	
Gap analysis conducted by	
Gap analysis participants	

Key

-  Green – minimum compliance
-  Amber – partial compliance
-  Red – no compliance

This gap analysis tool is aligned with standard ISO 9001:2015, *Quality Management Systems – Requirements*, and it is imperative that gap analysis is undertaken with due reference to the standard. The gap analysis tool is divided into seven sections, which reflect the contents of ISO 9001:2015.

A traffic light system is used to highlight the gaps that exist between the requirements of the standard and the current management system. The traffic light system indicates the level of compliance with the specific requirements of the standard. Throughout this gap analysis, the term quality management system (QMS) embraces all the activities of the QMS/organization. For the purposes of the exercise, the terms management system, QMS and organization can be interchanged and are considered to mean the same thing.

<i>Reference clause in ISO 9001:2015</i>	<i>Gap analysis question</i>	<i>Status</i>	<i>Comments</i>
4. Context of the organization			
4.1 Understanding the organization and its context	1. Has the QMS determined the external and internal issues (values, culture, knowledge and performance) that affect the ability to achieve intended results?	  	
	2. Has the QMS considered international, national, regional or local issues arising from legal, technological, competitive, market, cultural, social and economic environments?		
	3. How often does the QMS monitor and review these issues?		

<i>Reference clause in ISO 9001:2015</i>	<i>Gap analysis question</i>	<i>Status</i>	<i>Comments</i>
4.2 Understanding the needs and expectations of interested parties	4. Who are the interested parties (stakeholders); for example, customers, owners, people in an organization, suppliers, bankers, unions, partners or society (ISO 9000:2015)?		
	5. Has the QMS determined all the interested parties' requirements?		
	6. Does the QMS monitor and review stakeholder needs, and if so, what process is used and how frequently is it performed?		
4.3 Determining the scope of the quality management system	7. Has the QMS scope been clearly defined? Have the following been considered: external/internal issues (clause 4.1), requirements of interested parties (clause 4.2) and products and services of the organization?		
	8. Does the scope state the products/services covered? Does it justify any areas not applicable and is it available as documented information?		
4.4 Quality management system and its processes	9. Have the processes (inputs/outputs and sequences/interactions) required to deliver the outcomes been determined?		
	10. Have key performance indicators (KPIs) and methods of measurement been established to ensure the effectiveness of processes?		
	11. Have the resources required to support each process and their availability been determined?		
	12. Have responsibilities and authorities been determined for all processes?		
	13. Have risks and opportunities been identified (with respect to clause 6.1)?		
	14. Are processes evaluated and improved?		
	15. Is documented information retained to provide confidence that processes are being carried out as planned?		
5. Leadership			
5.1 Leadership and commitment	Does top management:		
	16. Promote a process approach and risk-based thinking?		
	17. Ensure resources are available as appropriate?		
	18. Ensure intended results are achieved?		
	19. Promote improvement?		
	20. Ensure customer/statutory/regulatory requirements are determined, understood and consistently met?		
	21. Ensure risks and opportunities that can affect conformity of products/services and the ability to enhance customer satisfaction are determined and addressed?		
	22. Ensure the focus on enhancing customer satisfaction is maintained?		
5.2 Policy	23. Has a quality policy been formulated and communicated to all staff?		

<i>Reference clause in ISO 9001:2015</i>	<i>Gap analysis question</i>	<i>Status</i>	<i>Comments</i>
5.3 Organizational roles, responsibilities and authorities	24. Does top management ensure that responsibilities and authorities for staff are assigned, communicated and understood within the organization? In particular, are responsibilities and authorities assigned for ensuring processes deliver their intended outputs, reporting on opportunities for improvement and ensuring the promotion of customer focus?		
6. Planning			
6.1 Actions to address risks and opportunities	25. Does the QMS have a process to identify risks and opportunities, including their control and treatment?		
	26. Does the risk and opportunities process consider internal/external issues and the needs and expectations of interested parties?		
	27. Is this process undertaken on a scheduled basis and on a needs basis?		
	28. Is this process used to ensure that products/services conform to defined requirements or achieve improvements?		
	29. Is this process documented and communicated to all staff?		
6.2 Quality objectives and planning to achieve them	Are the objectives and KPIs:		
	30. Relevant to the conformity of products/services and customer satisfaction?		
	31. Aligned with defined requirements?		
	32. Measurable?		
	33. Monitored and communicated?		
	34. Maintained as documented information and updated as appropriate?		
	When planning how to achieve these objectives, is it determined:		
	35. What tasks and processes will be conducted and what resources are required?		
	36. Who will be responsible for achieving the objective and when?		
6.3 Planning of changes	37. How the results of the planning will be evaluated?		
	38. Is change undertaken in a planned manner?		
	39. Does the QMS consider the purpose of the change and potential consequences including associated risks?		
	40. Does the QMS consider the allocation of responsibilities/authorities and availability of resources?		
7. Support			
7.1 Resources 7.1.1 General	41. Are existing internal resource capabilities and limitations determined, and which, if any, are sourced externally?		
	42. Has the necessary infrastructure been determined, provided and maintained for QMS operations, to assure conformity of products/services and customer satisfaction?		
7.1.2 People	43. Has the QMS determined and provided the people needed for the operation of its processes and to achieve conformity of products/services?		

<i>Reference clause in ISO 9001:2015</i>	<i>Gap analysis question</i>	<i>Status</i>	<i>Comments</i>
7.1.3 Infrastructure	44. Has the QMS determined, provided and maintained the infrastructure (buildings, equipment, hardware, software, communications, information technology systems) necessary for operations and to assure conformity of products/ services and customer satisfaction?		
7.1.4 Environment for the operation of processes	45. Has the necessary process environment (social, for example, non-discriminatory, calm or non-confrontational; psychological, for example, stress-reducing, burnout prevention or emotionally protective; and physical, for example, temperature, heat, humidity, light, airflow, hygiene or noise) been determined, provided and maintained for QMS operations, to assure conformity of products/ services and customer satisfaction?		
7.1.5 Monitoring and measuring resources	46. Have the monitoring and measuring resources needed to verify the conformity to product requirements been determined, to ensure they are fit for purpose?		
7.1.5.1 General	47. Is appropriate documented information as evidence of fitness for purpose of monitoring and measuring devices maintained?		
7.1.5.2 Measurement traceability	48. Is measurement traceability required?		
	49. Has measuring equipment been calibrated or verified (or both) at specified intervals against measurement standards traceable to international (or national) standards?		
	50. Has measuring equipment been identified in order to determine its status and safeguarded from adjustment/damage/deterioration that could invalidate the calibration status?		
	51. If the measuring equipment is found to be unfit for purpose, has the validity of previous measurement results been investigated and appropriate action taken?		
7.1.6 Organizational knowledge	52. Has the corporate knowledge necessary for operation of the organization to assure conformity of products/services and customer satisfaction been determined?		
	53. Is corporate knowledge maintained, protected and made available as necessary?		
	54. How is it ensured that the current knowledge base is kept up to date including emerging trends?		
7.2 Competence	55. Has the necessary competence of QMS staff been determined?		
	56. Is it ensured that the staff is competent on the basis of appropriate education, training or experience?		
	57. Is appropriate documented information as evidence of competence maintained?		
7.3 Awareness	58. Is the staff aware of the relevant objectives and effectiveness in contributing to them?		
7.4 Communication	59. Has a communications plan relevant to internal and external stakeholders been developed?		
7.5 Documented information	60. Has the QMS documented information that has been determined as being necessary for the effectiveness of the management system?		
7.5.1 General			

<i>Reference clause in ISO 9001:2015</i>	<i>Gap analysis question</i>	<i>Status</i>	<i>Comments</i>
7.5.2 Creating and updating	When creating and updating documented information, are the following ensured:		
	61. Identification and description (title, date, author, reference number, currency, version number)?		
	62. Format and media (language, software version, graphics, paper, electronic)?		
	63. Review and approval for suitability and adequacy?		
7.5.3 Control of documented information	Is documented information controlled to ensure:		
	64. It is available and suitable for use, where and when it is needed?		
	65. It is adequately protected (for example, from loss of confidentiality, improper use or loss of integrity)?		
	66. Distribution, access, retrieval and use?		
	67. Who has permission to view the documented information?		
	68. Who has permission and authority to change the documented information?		
	69. Storage and preservation, including preservation of legibility?		
	70. Retention and disposal?		
8. Operation			
8.1 Operational planning and control	71. Does the QMS plan, implement and control the processes needed to mitigate risks and identify opportunities?		
	72. Are criteria established for these processes?		
	73. Is documented information retained to provide confidence that the processes have been carried out as planned?		
8.2 Requirements for products and services	74. Is there a process for interacting with potential or existing customers to determine their requirements relating to products/services?		
8.2.1 Customer communication	75. Does communication with customers include: information relating to products/services; handling enquiries, contracts and orders including changes; obtaining feedback including complaints; handling/controlling customer property; and establishing specific requirements for contingency actions, when relevant?		
8.2.2 Determining the requirements for products and services	76. Has the QMS determined the requirements specified by the customer including the requirements for delivery and post-delivery activities?		
	77. Has the QMS determined the statutory and regulatory requirements applicable to the products/services?		
8.2.3 Review of requirements for products and services	78. Does the QMS review the requirements related to the products/services?		
	Are reviews conducted (prior to commitment to supply products/services to the customer) to ensure that:		
	79. Requirements are defined and agreed?		
	80. Contract requirements differing from those previously expressed are resolved?		
	81. The organization is able to meet the defined requirements?		

<i>Reference clause in ISO 9001:2015</i>	<i>Gap analysis question</i>	<i>Status</i>	<i>Comments</i>
8.2.4 Changes to requirements for products and services	82. When changes to requirements are needed, has the relevant documented information been amended and relevant persons informed of the changes?		
8.3 Design and development of products and services 8.3.1 General	83. Has the QMS established, implemented and maintained a design and development process?		
8.3.2 Design and development planning	84. In determining the stages and controls for this process, are the following considered: nature, duration and complexity of design and development activities; required process stages including applicable review stages; internal and external resources needed; and need to involve customers and users?		
8.3.3 Design and development inputs	85. Does the QMS determine the requirements essential for the products/services to be designed and developed? These include functional and performance requirements, statutory and regulatory requirements, standards or codes of practices the organization has committed to implement and the potential consequences of failure due to the nature of the products/services.		
	86. Does the QMS retain documented information on all design and development inputs?		
8.3.4 Design and development controls	87. Does the QMS have controls in place for design and development activities? These include functional and performance requirements, statutory and regulatory requirements, standards or codes of practices the organization has committed to implement and the potential consequences of failure due to the nature of the products/services.		
8.3.5 Design and development outputs	88. Does the QMS ensure that design and development outputs meet the input requirements, are adequate for the provision of products/services and include monitoring, as appropriate?		
	89. Does the QMS retain documented information on all design and development outputs?		
8.3.6 Design and development changes	90. Does the QMS identify, review and control any changes made during (or after) the design and development of products/services to ensure no adverse impact on conformity to requirements?		
	91. Does the QMS retain documented information on changes such as design and development changes, review results, authorization for any changes and actions to prevent adverse impacts?		
8.4 Control of externally provided processes, products and services 8.4.1 General	92. How is it ensured that externally provided products/services conform to specified requirements?		
	93. Is documented information on these evaluation activities retained?		

<i>Reference clause in ISO 9001:2015</i>	<i>Gap analysis question</i>	<i>Status</i>	<i>Comments</i>
8.4.2 Type and extent of control	94. Has it been ensured that externally provided processes remain within the control of the management system?		
	95. Have the controls that apply to the provider and the supplied product/service both been defined?		
	96. Has the potential impact of externally provided products/services on the ability to meet customer/statutory/regulatory requirements been defined?		
	97. Have risk and potential opportunities been identified?		
	98. Has the degree to which the control of an externally provided process is shared between QMS and the provider been identified?		
	99. Has the QMS established and applied criteria for the evaluation, selection and re-evaluation of external providers based on QMS requirements?		
	100. Does the QMS maintain documented information describing the results of evaluations?		
8.4.3 Information for external providers	Are reviews conducted (prior to commitment to supply products/services to the customer) to ensure that:		
	101. Requirements for approval or release of products/services, procedures, processes or equipment are met?		
	102. Requirements for competence of personnel, including necessary qualifications, are met?		
	103. Control and monitoring of external provider performance is applied by the QMS?		
	104. Verification activities that the QMS or its customer intend to perform at external provider premises are conducted?		
	105. Requirements for handling of external provider property provided to the QMS are met?		
	106. Requirements for handling of external provider property provided to the QMS are met?		
8.5 Production and service provision	107. Is service provision performed under controlled conditions and does it include: documented information defining characteristics of products and results to be achieved; using monitoring and measurement at appropriate stages to ensure acceptance criteria are met; suitable infrastructure and environment; competent persons (including required qualifications); actions to prevent human error; and implementation of release, delivery and post-delivery activities?		
8.5.1 Control of production and service provision			
8.5.2 Identification and traceability	108. Are outputs uniquely identified?		
	109. Is documented information retained?		
8.5.3 Property belonging to customers or external providers	110. Does the QMS identify, verify, protect and safeguard external provider property?		
	111. If property is lost, damaged or otherwise found unsuitable, is it reported and is documented information retained?		
8.5.4 Preservation	112. Is the preservation of products during processing and delivery ensured to the intended destination, in order to maintain conformity to requirements?		

<i>Reference clause in ISO 9001:2015</i>	<i>Gap analysis question</i>	<i>Status</i>	<i>Comments</i>
8.5.5 Post-delivery activities	113. Where applicable, does the organization determine and meet requirements for post-delivery activities associated with the nature and intended lifetime of the products/services?		
8.5.6 Control of changes	114. Is change undertaken in a planned and systematic manner?		
	115. Are the potential consequences taken into account?		
	116. Is integrity of products/services ensured?		
	117. Does the QMS maintain documented information describing the results of changes and of the personnel authorizing the change?		
8.6 Release of products and services	118. Does the QMS ensure that the release of products/services does not proceed until planned arrangements for verification of conformity have been satisfactorily completed?		
	119. Does the QMS maintain documented information of the person(s) authorizing the release of products/services for delivery to customers?		
8.7 Control of nonconforming outputs	120. Does the QMS ensure that products/services that do not conform to requirements are identified and controlled to prevent their unintended use or delivery?		
9. Performance evaluation			
9.1 Monitoring, measurement, analysis and evaluation 9.1.1 General	Does the QMS determine and take into consideration, any risks and opportunities in terms of what needs to be monitored and measured in order to:		
	121. Demonstrate conformity of products/services to requirements?		
	122. Evaluate customer satisfaction?		
	123. Determine the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results?		
	124. Does the QMS retain appropriate documented information records as evidence of the results?		
9.1.2 Customer satisfaction	125. Does the QMS monitor and record levels of customer satisfaction?		
9.1.3 Analysis and evaluation	Does the QMS analyse and evaluate the results obtained from monitoring and measurement to:		
	126. Ensure that the operation and control of processes is effective?		
	127. Identify improvements?		
	128. Are the results of analysis and evaluation used as an input to the management review process?		
9.2 Internal audit	129. Does the QMS conduct, plan and schedule internal audits?		
	130. Has the QMS selected auditors that ensure objectivity and impartiality?		
	131. Does the QMS ensure audit findings are reported to the relevant management?		
	132. Does the QMS retain documented information as evidence of audit results and that the audits have been conducted?		

<i>Reference clause in ISO 9001:2015</i>	<i>Gap analysis question</i>	<i>Status</i>	<i>Comments</i>
9.3 Management review	133. Does the QMS conduct management reviews on a scheduled and needs basis?		
9.3.1 General 9.3.2 Management review inputs	134. Do the management reviews inputs include: customer satisfaction feedback, status of objectives, performance of processes, issues with non-conformities and corrective actions, results of monitoring and measuring audit findings, and performance of external providers?		
9.3.3 Management review outputs	135. Do the management review outputs include: opportunities for improvement, changes to the QMS and additional resource requirements?		
10. Improvement			
10.1 General	136. Does the QMS identify opportunities for improvement, in particular, to enhance customer satisfaction?		
10.2 Nonconformity and corrective action	137. What actions does the QMS take to control, correct and deal with the consequences of a non-conformity?		
	Does the QMS evaluate the need for action to eliminate the causes of the non-conformity to ensure it does not occur again by:		
	138. Determining the causes of the non-conformity?		
	139. Implementing any action required so that it does not recur or occur elsewhere?		
	140. Reviewing the effectiveness of any corrective action taken?		
	141. Retaining documented information as evidence of the nature of the non-conformities and any subsequent actions taken?		
10.3 Continual improvement	142. Does the QMS continually endeavour to improve the suitability, adequacy and effectiveness of its management system?		
	Does the QMS improve processes and products/ services by responding to:		
	143. Results of analysis of data?		
	144. Changes in identified risks?		
	145. Identification of new opportunities?		

APPENDIX 20. GAP ANALYSIS FINDINGS (PART B)

<i>Gap analysis findings</i>	
Quality management system (QMS)	
Scope of gap analysis	
Gap analysis time period	
Gap analysis completion date	
Gap analysis conducted by	
Gap analysis participants	
Notes	

4 – Context of the organization				
<i>Reference clause in ISO 9001:2015</i>	<i>Gap identified</i>	<i>Proposed remedial action</i>	<i>Officer responsible</i>	<i>Gap filled date</i>
5 – Leadership				
<i>Reference clause in ISO 9001:2015</i>	<i>Gap identified</i>	<i>Proposed remedial action</i>	<i>Officer responsible</i>	<i>Gap filled date</i>
6 – Planning				
<i>Reference clause in ISO 9001:2015</i>	<i>Gap identified</i>	<i>Proposed remedial action</i>	<i>Officer responsible</i>	<i>Gap filled date</i>

7 – Support				
<i>Reference clause in ISO 9001:2015</i>	<i>Gap identified</i>	<i>Proposed remedial action</i>	<i>Officer responsible</i>	<i>Gap filled date</i>
8 – Operation				
<i>Reference clause in ISO 9001:2015</i>	<i>Gap identified</i>	<i>Proposed remedial action</i>	<i>Officer responsible</i>	<i>Gap filled date</i>
9 – Performance evaluation				
<i>Reference clause in ISO 9001:2015</i>	<i>Gap identified</i>	<i>Proposed remedial action</i>	<i>Officer responsible</i>	<i>Gap filled date</i>
10 – Improvement				
<i>Reference clause in ISO 9001:2015</i>	<i>Gap identified</i>	<i>Proposed remedial action</i>	<i>Officer responsible</i>	<i>Gap filled date</i>

APPENDIX 21. GENERIC HANDOVER/TAKEOVER PROCEDURE

"QMS" handover/takeover

Name:

Job title:

Position number:

Supervisor:

Date of handover note: __ / __ / __

Duration of assignment: days/weeks/months

Start date: __ / __ / __

End date: __ / __ / __

Brief description of duties (as per duty statement):

Supervisor and reporting procedures:

Financial delegations and responsibilities:

Regular/re-occurring meetings, reports or procedures:

Key documents/reference material to read (attach when possible):

Status of recent and current projects/reports/meetings:

Where to find files (hard copy and electronic):

Calendar of major activities and/or events (optional):

Any significant issues that present a risk to "QMS" activities:

Any significant issues that will affect the ongoing development and sustainability of "QMS":

Contacts (internal and external):

<i>Name</i>	<i>Organization</i>	<i>Phone</i>	<i>Email</i>	<i>Comments</i>

Your contact information after departure:

Phone: **Email:**

Outgoing officer:

Name (print):

Signature: **Date:** __ / __ / __

Incoming officer:

Name (print):

Signature: **Date:** __ / __ / __

APPENDIX 22. OPPORTUNITIES REGISTER

[illegible]

[illegible]

ANNEX 1. AERONAUTICAL METEOROLOGICAL SERVICES

1. **Drivers for adopting a quality management approach – WMO and International Civil Aviation Organization perspectives**

1.1 The adoption of a quality management (QM) approach to the delivery of products and services of National Meteorological and Hydrological Services (NMHSs) has been due to a number of drivers. The initial driver was the requirements of the International Civil Aviation Organization (ICAO) for the delivery of aeronautical meteorological services. There is a long-standing formal working arrangement between ICAO and WMO, as described in *Agreements and Working Arrangements with other International Organizations* (WMO, 2002, Chapter 2).

1.2 Quality-related standards and recommended practices in ICAO Annex 15 – *Aeronautical Information Services* were first introduced in November 1997 (ICAO, 1997). It was recognized that in the field of meteorological services for international air navigation, QM had become increasingly important, and that there was a need for a properly organized quality system to ensure continued high quality of data and products provided by aeronautical meteorological services.

1.3 Provisions for QM were introduced in Amendment 72 to ICAO Annex 3 – *Meteorological Service for International Air Navigation* (ICAO, 2001) and the *Technical Regulations, Volume II – Meteorological Service for International Air Navigation* (WMO, 2001) in November 2001. These provisions articulated recommended practices concerning quality control and management of meteorological information supplied to users and in the training of aeronautical meteorological personnel. Among these practices is the recommended conformity with the International Organization for Standardization (ISO) 9000 series of quality assurance standards.

1.4 To assist WMO Member NMHSs and ICAO contracting States in implementing quality management systems (QMSs), in 2006, WMO and ICAO jointly developed and published a *Guide to the Quality Management System for the Provision of Meteorological Service for International Air Navigation* (updated in 2014; WMO/ICAO, 2014). The focus of that guide was to facilitate the design, development and implementation of a QM system compliant with ISO 9000 by the aeronautical meteorological services within an ISO 9001:2008, *Quality Management Systems – Requirements* (ISO, 2008) QMS framework.

1.5 Amendment 75 to Annex 3 (ICAO, 2010), which became applicable in November 2010, raised the recommended practice pertaining to QMSs for aeronautical meteorology to the status of a standard, that is, a binding requirement for all Members/contracting States. At the time, it was recognized that many Member NMHSs were not ready to implement a QMS and so it was decided that the ICAO standard pertaining to a QMS for aeronautical meteorological service provision should be effective from 15 November 2012. The standard is complemented by the recommendation for the QMS to be in conformity with the ISO 9000 series of quality assurance standards and to be certified by an approved organization.

1.6 The first edition of the *Guide to the Implementation of Quality Management System for National Meteorological and Hydrological Services* (WMO, 2013) provided a step-by-step practical guide to developing a QMS for NMHSs, which enables certification of compliance to ISO 9001:2008, *Quality Management Systems – Requirements*. The introduction of ISO 9001:2015, *Quality Management Systems – Requirements* (ISO, 2015c) has been the catalyst for this current update of the Guide.

1.7 WMO continues to strongly support the adoption of a QM approach for the delivery of meteorological products and services for the international civil aviation/air transport sector. It also recognizes development in other sectors where partner organizations are requesting the implementation of QMSs for the delivery of products and services applicable to those sectors.

1.8 It is of note that the WMO Aeronautical Meteorology Programme, underpinned by strong support from the WMO Secretariat, has played and continues to play a leading

and proactive role in the adoption of a QM approach to the delivery, by WMO Members, of aeronautical meteorological products and services conforming to the evolving requirements of ICAO.

1.9 There is a chapter specifically focused on QM in *Technical Regulations (WMO-No. 49), Volume I, General Meteorological Standards and Recommended Practices* (WMO, 2015), which was approved for inclusion at the sixty-ninth session of the Executive Council in May 2017 (WMO, 2017).

1.10 WMO continues to recognize the urgency associated with supporting the implementation of QMSs by WMO Member NMHSs in their services for international civil aviation. It also recognizes the developments in other application areas where partner organizations are mandating the implementation of QMSs. Overall, WMO recognizes the high importance of having QMSs underpinning many aspects of the work of WMO and its Members.

2. Aviation and the integration of management systems

2.1 On its safety management – standards and recommended practices (SARPS) web page, ICAO notes that the safety management SARPS:

are intended to assist States in managing aviation safety risks, in coordination with their Service Providers. Given the increasing complexity of the global air transportation system and its interrelated aviation activities required to assure the safe operation of aircraft, the safety management provisions support the continued evolution of a proactive strategy to improve safety performance. The foundation of this proactive safety strategy is based on the implementation of a State safety programme (SSP) that systematically addresses safety risks, in agreement with the implementation of the safety management systems (SMS) by the service providers.

(ICAO, 2017)

2.2 There is no requirement specifically stated in ICAO Annex 3 referring to SMSs and the delivery of aeronautical meteorological services. However, there is merit in providing some broad information in terms of the relationship between a QMS and an SMS that WMO QM practitioners may find useful.

2.3 An SMS determines and continually improves an organization's safety position and performance, through a systematic approach to managing safety and mitigating safety risks, including the necessary organizational structures, accountabilities, policies and procedures.

2.4 An SMS focuses on safety and exposure to risk, whereas a QMS focuses on providing a sound management framework that encapsulates all aspects of the organization's activities.

2.5 Concerns may be raised as to how the SMS and QMS work together or are integrated. However, an integrated management system (IMS) integrates all of an organization's systems and processes into one framework, enabling an organization to work as a single unit with unified objectives. As an example, an IMS could consist of a combination of the following: ISO 9001:2015 – *Quality Management System – Requirements* (ISO, 2015c), ISO 14001:2015 – *Environmental Management Systems – Requirements with Guidance for Use* (ISO, 2015a), ISO/IEC 27001:2013 – *Information Technology – Security Techniques – Information Security Management Systems – Requirements* (ISO/IEC, 2013) and/or ISO 45001 – *Occupational Health and Safety* (ISO, in preparation).

2.6 The following are key features of an SMS that reflect strong alignment with a QMS:

- Senior management commitment
- Safety policy
- Safety information

- Safety as a core value
- Safety goals
- Hazard identification and risk management
- Safety reporting system
- Safety audit/assessment
- Accident and incident reporting and investigation
- Safety orientation and recurrent training
- Emergency response plan
- Documentation

2.7 Practical experience has shown that integration of an SMS and a QMS is relatively straightforward and complementary. Evaluation of the safety impact of meteorological products and services for different customers will be a useful first step. The resulting IMS will enhance the overall viability and sustainability of an organization.

ANNEX 2. GLOSSARY

The quality management system (QMS) terminology, vocabulary and definitions used throughout this Guide are those of the International Organization for Standardization (ISO), in particular, those identified in ISO 9000:2015, *Quality Management Systems – Fundamentals and Vocabulary* (ISO, 2015b). The meteorological and aviation terminology, vocabulary, abbreviations and definitions used are those of WMO, the International Civil Aviation Organization and other relevant organizations as appropriate.

A brief description of the quality management terminology most frequently used is provided below; however, definitions may vary slightly depending on the industry and community sector.

Certification and registration	Depending on the region in which the WMO Member is located, the terms “certification” or “registration” may be used interchangeably. For the purposes of this Guide, certification is used throughout. Certification refers to the issuing of written assurance (the certificate) by an independent external conformity assessment body that it has audited a management system and verified that it conforms to the requirements specified in the relevant standard.
Control	Activities associated with ensuring a process provides consistent outputs at the required level of quality.
Customer	Within WMO and elsewhere, clients and customers are usually referred to as “users”. However, the ISO family of standards exclusively uses the term “customer” in order to ensure clarity and consistency. It should be noted that a QMS may have internal and external customers.
External provider	Provider of products or services that is external to the QMS but which may be internal or external to the organization.
Input/output	An input is an element or component that is added to a process to assist in meeting a specified requirement (examples include data, materials, knowledge or competent staff). An output is a specific product or service that is expected to be produced by a process (examples include an aerodrome warning or forecast).
Integrated management system (IMS)	Integrates all of an organization’s systems and processes into one framework, enabling the organization to work as a single entity with unified objectives.
Interested party/stakeholder	Any individual or organization that can affect the activities of WMO programmes and WMO Member National Meteorological and Hydrological Services (NMHSs), or any individual or organization that can be affected by the activities of WMO programmes and WMO Member NMHSs.
Organization	Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objective. That is, any WMO programme, constituent body or Member NMHS that develops and implements a QMS.
Quality	There are many definitions and interpretations of “quality”; however, all have one element in common: quality refers to the perception of the extent to which a product or service meets customer expectations. It should be noted that quality has no explicit meaning unless it is related to a specific set of requirements. To highlight this, ISO defines quality “as the degree to which a set of inherent characteristics fulfils requirements”.

Quality assurance	Aims to instil confidence that quality requirements have been met. It involves the systematic monitoring and evaluation of the processes associated with the generation of a product or service.
Quality control	Aims to ensure that quality requirements have been fulfilled prior to the dissemination of a product or the delivery of a service.
Quality improvement	Realized due to the successful development and implementation of a QMS.
Quality management (QM)	A process that focuses not only on the quality of the product or service but also on the means to achieve it. It is centred on four activities: quality planning, quality control, quality assurance and quality improvement.
Quality management system (QMS)	Organizational structure, procedures, processes and resources needed to ensure the delivery of an organization's products and/or services to its customers. WMO Member NMHSs are strongly encouraged to undergo third-party (external) audit to achieve certification of compliance with ISO 9001:2015, <i>Quality Management Systems – Requirements</i> (ISO, 2015c).
Service level agreement (SLA)	A contract between a service provider (either internal or external) and a customer that defines the level of service expected from the service provider. As its purpose is specifically to define what the customer will receive, for instance in terms of timeliness, accuracy, resolution and frequency of issuance, an SLA is output based. It has the potential to be a key management tool for a QMS in terms of interactions with external providers (see clause 8.4 of ISO 9001:2015).
Validation and verification	In NMHSs, operational environment verification is traditionally used to ascertain the quality of a forecast and warning product after it has been delivered. However, in the ISO environment, verification of a product occurs prior to delivery, and the quality is of the product validated after delivery.

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For more information, please contact:

World Meteorological Organization

7 bis, avenue de la Paix – P.O. Box 2300 – CH 1211 Geneva 2 – Switzerland

Communication and Public Affairs Office

Tel.: +41 (0) 22 730 83 14/15 – Fax: +41 (0) 22 730 80 27

Email: cpa@wmo.int

public.wmo.int